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Articoli/Articles

THE INFLUENCE OF PRUSSIAN DRUG LEGISLATION ON THE FIRST GERMAN PHARMACOPOEIA 1872

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SUMMARY

When the new Kaiserreich was proclamed (1871) new rules were stated to organize all the 20 states. A unified Pharmacopoeia was also created. A committee was constituted by the Federal Parliament and the first edition was published in 1872, and in the revised form (editio altera) in 1882, the first one was the continuation of the series of Prussian Pharmacopoeia editions (1799-1862) which resolved many problems concerning the uniformity of weights and measurements, language, analytical assays and prescriptions.

Following the Prussian-French war of 1870/71, the proclamation of the new *Kaiserreich*, the German Empire (without Austria) took place at Versailles on January 18th, 1871. Only four months later, the *Bundesrat* (Federal parliament of the German states) installed a pharmacopoeial committee in order to prepare an universal German pharmacopoeia (excluding Austria = *klein-deutsch*), which appeared on June 1st, 1872 and came into force on November 1st, 1872. Its name was Pharmacopoea Germanica, later called *editio prima*, the *editio altera* following in 1882. Since 1891, third edition, it was written in German language, since then being called *Deutsches Arzneibuch* (*DAB*); the first edition from now on being called *DAB 1*.

Obviously, the twelve months of preparation in 1871/72 could not bring together anything basically new, and the question

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arises where the prototype of this epochmaking pharmacopoeia may be found. There were many smaller and bigger states which since 1871 composed the German Empire². Some of these states had put into force their particular pharmacopoeia few years ago, namely

Prussia in 1862/63. Bayaria in 1859.

Hesse in 1860.

Hanover in 1861

After the Prussian-Austrian war of 1866 and the following annexation, the states of Norddeutscher Bund, including Hanover, had been forced to adopt the Prussian pharmacopoeia of 1862^{3}

These and all other states of the Empire introduced in 1872 the new German pharmacopoeia. Since health administration remained with the single state, each one had to put it in force separately, although the Reichskanzler had done it for the Reich as a whole. These were altogether 20 states:

Prussia Sachsen-Meiningen

Baden Lübeck Bavaria Bremen Hesse Hamburg Saxonia Waldeck Württemberg Reuß

Elsaβ-Lothringen Braunschweig

Mecklenburg Schwarzburg-Sondershausen Sachsen-Anhalt Sachsen - Coburg - Gotha

Sachsen-Weimar Oldenburg,

most of them having had their own traditions in pharmacopoeial regulations. The historiography to this day, however, sees the first Ph. Germanica largely as a result and continuation of the series of seven Prussian Pharmacopoeia editions 1799-1862. A critical comparison with the remaining states has been missing so far4.

Following the research of Wolfgang Schneider from 1959 it is clear, however, that it was not only the Prussian tradition which shaped the first Ph. Germanica, but also some federal inspiration, which surprisingly originated not from the states administration, but from the profession of pharmacists (Apotheker) throughout the whole territory of Germany (even including Austria)3. To understand this, it is necessary to look briefly on the history of the preceding period.

Since the time of Napoleonic wars through the Vormärz period, the 1848 revolution and the restauration after 1849/50, the all-German strive after national and cultural unity had included a unified pharmacopoeia as a common legal codex. This was expressed for instance in:

1830: on the meeting of the Gesellschaft deutscher Naturforscher und Ärzte, the only all-German society of naturalists, scientists and physicians⁵;

1818: in the first volume of the codex medicamentarius Europaeus, edited at Leipzig6:

before 1848 (Vormärz): in Geiger and Mohr's Pharmacopoea Universalis 1845 as well as in the Codex der Pharmakopöen, edited in Leipzig 1844-47 and in many publications⁷;

1855 - 1865: in the elaborate work of the newly established Allgemeiner Deutscher Apothekerverein (the Association of northern and southern German pharmaceutical societies) who organized a pharmacopoeial committee being composed of professional pharmacists only, neither physicians nor state officials were included. The pharmacists came from all major German states, including Austria8, and went much further than all the authors of the preceding Universal-Pharmakopöen, who had restricted themselves to putting together a comparison of already existing pharmacopoeial standards7.

The Apotheker-Verein, in constrast, prepared in 1865 (1867) the so-called Pharmacopoea Germaniae, which at once was regarded by the whole profession as the best possible pharmacopoeia of all what was available, having only the one disadvantage of not being made by any state administration9. It was regarded as a private enterprise and did not succeed in coming into force after the 1866 war, with the exception of the Kingdom of Saxony where it was made legal in 1867.

However, it was this professional, non-state, federalistic Pharmacopoea Germaniae which was used as the prototype for the DAB 1 and which enabled the committee of 1871/72 to come to an end with their work surprisingly quickly.

If we compare this Ph. Germaniae of 1865 with the preceding Pharmacopoea Borussica of 1862, we find a great deal of convergence in all central and then controversial questions. These were

1. The weights problem: (in the total of German pharmacy tradition there were no measures, only weights).

In the 1860ies, dozens of differing commercial as well as pharmaceutical weight systems were to be found in Germany, although everybody expected the French decimal gram-system would be introduced soon (which happened for the *Reich* in 1872). Anticipating this, the last Prussian as well as the *Germaniae* pharmacopoeia spoke in their prescriptions always of parts of weight (partes), giving the *libra* (pound) as 500 gram of French weight¹⁰;

2) The language problem:

Both pharmacopoeias agreed on Latin language, whereas the last editions in the kingdoms of Bavaria and Hanover had been in German¹¹;

3) The prescription problem:

By tradition and for standardization purposes, it had been regarded important to give in the legal pharmacopoeia exact prescriptions for preparing not only composed, but also simple medicaments such as chemicals including isolated plant products like alcaloids. The pharmacist used to be obliged to follow these prescriptions even if it was possible to buy the products - much cheaper - from the already existing pharmaceutical/chemical industry. Both, the Prussian as well as the Ph. Germaniae omitted most of these prescriptions in 1862/1865, leaving the decision as to the choice of the particular prescription to the scientific competence of the pharmacist (not all of

them - although many - having a university training, which became obligatory for the Empire not before 1875)¹²;

4) The problem of analytical assay:

For standardization and safety reasons, it was the challenge of the time to give precise analytical procedure for identity and quality control at least for those simple drugs which the pharmacist did not prepare himself but bought from the manufacturer. To us, it seems to be inconsequent, that there were analytical procedures not given to that extent which seems necessary in either the Prussiae or Germaniae Pharmacopoeia¹³. In the other Pharmacopoeias, qualitative (e. g. Bavaria, Hanover) and quantitative (e. g. Württemberg) assays had been given much more profusely. Nevertheless, the Ph. Germaniae gives a compromise and has about twice as much articles in the list of analytical reagents and three times as many quantitative assays compared with the last Prussian edition of 1862¹⁴.

Even if we are still lacking an over-all historical comparison of the influence of all the many particular pharmacopoeias, we may ascertain that, on the whole, the Ph. Germaniae and with it the first Pharmacopoea Germanica (DAB 1) was a child much more of the Ph. Borussica than of any other series of pharmacopoeias in the German countries¹⁵. We have to conclude, that it was not only the political predominance of Prussia (particularly obvious after the exclusion of Austria from the *Reich*) which explaines the predominance of the Prussian pharmacopoeia over all the other ones - however competent in particular areas of pharmaceutical stan-dards they may have been.

This raises the question if drug administration and drug legislation was particularly excelling in Prussia by tradition. Does the fact, that all professionals in the 1860ies nationwide accepted the leading role of the Ph. Borussica suggest that this was true? Or did they only pay obeisance to the political hegemony? Anyway, historians have not yet investigated that question; there is no systematic comparison of legal and administrative aspects of drug control in Prussia relative to the other German states. Implicitly, historiography takes it for

granted that Prussia had the leading concepts and procedures for controlling the drug market and organizing pharmacy as a part of the health system as well as of the economic system¹⁶.

In Prussia, the reorganization of the health system in 1817 was part of the reforms of Stein/Hardenberg after the Napoleonic wars; health administration was no longer part of mercantilistic state politics but became part of the controversy between economic liberalism - support for free enterprise and drug manufacturers - on the one hand and health care as

duty of the state administration on the other¹⁷.

This conflict and its varying results are documented in the work of a number of Prussian state committees being concerned with drug regulations. They initiated a legislation which included Apothekerordnungen (pharmacist's laws), Apothekentaxen (obligatory pricelists for medicaments), the Pharmacopoea Borussica, the Edict über die Finanzen' (1811) resp. Gewerbeordnungen (trying to regulate the selling of medicaments by pharmacists and non-pharmacists, respectively). All of these discussions and regulations had their influence on the emerging German pharmacopoeia of 1872 (and its successors), which therefore is a mirror of not only the industrial development, but also of the corporate state as far as the influence of the profession of pharmacists (much less physicians) is reflected. Let us have a look on recent historical research on these committees.

It has long been known in pharmaceutical history that during the 18th century, the epoch of mercantilism and enlightened absolutism, legal regulation of pharmaceutical practice and drug control got more and more bureaucratized. This culminated in the Medical Law of 1725 in Prussia as well as in the first Prussian Pharmacopoeia of 1799, which replaced the earlier editions of the Brandenburg pharmacopoeia18. However, this was only a prelude to the bureaucratic efforts emerging in connection with the Prussian state reforms of Stein and Hardenberg in 1810. They have been historically explored by using archive material from the Prussian State Archives in Merseburg (then in the German Democratic Republic) not before

the 1970ies, and it is only since that time that we know more exactly how state administration, corporate interests, scientific development and industrial revolution acted together to remodel the drug market and its control, at least in Prussia since 1810. As far as we know, other German states (may be with the exception of Austria) did not organize similarly systematic efforts in order to modernize drug control as did the government of Prussia.

The starting point was the decision of 1810 to extend liberal laissez-faire on the drug market, as had been tried during the French revolution 1791 in France, but without success. The Edict über die Finanzen des Staates of 1811 gave all pharmacists the chance to open their own business, which was revoked in the same year by the Königliche Verordnung wegen der Anlegung neuer Apotheken¹⁹. This law gave for the whole century a very restricted system for licensing pharmacies and restricting the selling of medicaments to these konzessionierte pharmacies, whose economic existence was to be guaranteed by drug prices regulated by the state administration in the Arzneitaxe (price list of medicaments). The owners of these pharmacies had to follow the prescriptions in the pharmacopoeia as to buying articles from manufacturers or to prepare them in their own laboratories and/or to test them with means of scientific assav20.

During the following decades, all this regulation had to struggle with several economic, scientific and administrative problems which were treated by the committees established by the authorized ministry of the government. This was until 1817 the Innenministerium and its Departement der allgemeinen Polizei (Police department in the Home office), which was responsible for health affairs²¹. Since the administration reform of 1817 there existed a particular Ministerium für geistliche, Unterrichtsund Medizinalangelegenheiten (ministry for religious, educational and health affaires), in which the medical department took remarkable initiatives in order to organize a compromise between the differing interests of health care (supply with cheap as well as reliable medicaments), pharmacy owners and pharmacy employees, pharmaceutical industry and non-professional drug sellers (*Drogisten*)²². From to-days viewpoint, we have to conclude, that until the 1870ies the pharmaceutical profession (*Apotheker*) were able to preserve the biggest amount of traditional privileges and advantages for their profession, whereas since the 1880ies pharmaceutical industry was more and more able to influence administrative regulations of the drug market in the direction of their interests²³.

Drug regulations until 1871 were discussed, organized and formulated by the following committees:

1) Die Wissenschaftliche Deputation für das Medizinalwesen (Scientific Deputation for Health affaires).

It was founded in 1808 and started working in 1810 within the Home office/Department of the Interior, but since 1817 subordinated to the minister of religious affairs, education and health. The deputation was composed of state officials, about 10 physicians, all of Berlin, and three natural scientists who were according to the German tradition at that time very often trained pharmacists²⁴. The deputation functioned as pharmacopoeia committee until the fourth edition of the Prussian pharmacopoeia of 1829; for this purpose two pharmacist-shop owners from Berlin were admitted.

In this deputation fundamental questions about the admittance, prohibition and control of manufactured drugs, chemicals and composed medicines were discussed very vividly since 1820. In 1825, the leading state official, Langermann, even proposed the pharmaceutical industry to become an enterprise of the corporate pharmaceutical profession only, as far as pharmaceutical articles were concerned. The controversy about the industrialized drug market and the role of the pharmacist in it was more thoroughly discussed here than anywhere else²⁵. They offered privileges to the pharmacy owners and raised questions as to the calculation of drug prices (according to pharmacy or

manufacture production?) which resulted in very hard controversies around 1830.

2. Die Technische Kommission für Pharmazeutische Anlegenheiten (The Technical committee for pharmaceutical affairs) was the answer to these controversies; the question of drug prices in the official price-list (Arzneitaxe) as well as the role of industrial products and the raise of drug consumption during the cholera epidemic of 1831 sponsored its establishment in 1832²⁶.

The Kommission was established as a permanent pharmacopoeia committee, being responsible also for the *Arzneitaxe* and the elaboration of future *Apothekerordnungen* (pharmacy laws). It consisted of state officials of the ministry, several pharmacy owners and scientists, some of which were trained pharmacists as well. In this committee, the controversial discussion on pharmacy and its relation to industrial products continued; in the Vormärz area and the revolution of 1848 there continued discussion about products of the pharmaceutical industry to become pacemaker for cheaper drug prices and new pharmacopoeia politics²⁷. The results of these discussions are to be found in the Prussian pharmacopoeias of 1846, 1862 and to some extent in the Ph. Germaniae 1865/67 and Ph. Germanica 1872. They still were a compromise in favour of relatively free decision for the pharmacy owner if he wanted to prepare the medicaments himself or buy them from the manufacturers and now he wanted to test them by analytical procedure. Drug prices went down in the Arzneitaxe of 1863, but still were high enough in comparison with other German countries.

3. Die Arzneitax-Kommission (The Committee for preparing the official price-list for medicaments) was installed in 1815 in order to establish the fundamental principles according to which drug prices should be calculated²⁸. Through the historical research of I. Possehl we are informed about the extent to which pharmacy owners had been allowed to elaborate these principles. She gives us an account about the lively discussions in all areas of Prussia among pharmacists, which resulted in 1832

in the Tax-Committee becoming part of the *Technische Kommission* mentioned above.

One of the controversial issues as to price regulation for medicaments had been the question, if only pharmacy-owners or also pharmacist-employees should participate in this discussion. Whereas before 1832 there were two employees (as approbierte Apotheker, licensed pharmacists) members in the Tax-Kommission²⁹, this was not anymore true for the Technische Kommission. In connection with the Vormärz and 1848 events, employed pharmacists organized and made themselves heard by the government³⁰. This was no longer true in the reaction time of the 1850ies. However, the drastic reduction of drug prices in 1863 and connected permission by the pharmacopoeia to buy more products than before from manufacturers was one of the results of the propaganda made by the employees.

Without being able to give within this paper a more detailed summary of recent historical research on Prussian drug legislation during the 19th century I want to argue, that the influence of the Prussian on the emerging German drug standards in the pharmacopoeia was not only grounded in political power. Extensive and systematic elaboration of the problems related to drug market and control in diverse administration committees gave the Prussian tradition a kind of superiority within the health administrations of different German countries, which was recognized and acknowledged. That's what we see in the First Pharmacopoea Germanica 1872 and in its forerunner, the Pharmacopoea Germaniae 1865/67.

First German Pharmacopoeia

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Recensioni/Essay Reviews

SIRONI Vittorio A., Le officine della salute. Storia del farmaco e della sua industria in Italia. Laterza, Roma-Bari, 1992, pp. 274.

In coincidenza con la celebrazione del centenario della prima farmacopea ufficiale italiana viene pubblicata l'opera di Sironi dedicata alla nascita e sviluppo dell'industria del farmaco in Italia. Dalla rivoluzione farmacologica del secolo XIX, si passa all'industria *chimica* della prima metà del secolo XX, alla *esplosione farmacoterapica* del dopoguerra, con i problemi di brevettazione dei farmaci, d'interazione tra ricerca ed industria, di invasione delle multinazionali. Le notizie si susseguono dense, personaggi e date sono annotati in modo puntiglioso, ed è possibile trovare traccia delle principali vicende imprenditoriali.

Il tentativo è quello di mostrare queste vicende insieme con i fatti politici e con l'evoluzione socio-economica, di valutare quali inter-relazioni siano state condizionate dal potere politico. Nella premessa di Giorgio Cosmacini si fa cenno, in modo opportuno, alla domanda sostanziale sull'ultima evoluzione del mercato del farmaco: se cioè essa corrisponda sempre ad esigenze della medicina oppure se essa presenti novità che rispondono soprattutto ad esigenze commerciali. Si pensi al riguardo agli antibiotici definiti come di nuova generazione, ovviamente più costosi e più efficaci dei precedenti, ma anche drammaticamente più pericolosi per la selezione di ceppi batterici sempre più resistenti e di difficile eradicazione.

Nelle pagine fitte di nomi e date le notizie si susseguono fornendo una documentazione molto ricca, ma anche dispersiva. Si poteva giocare meglio su due piani, quello del testo (rivolto alla storia, cioè all'analisi logica degli avvenimenti) e quello delle note (nelle quali riversare nomi, date ed avvenimenti minori): così come il volume si presenta, non è agevole trovare un filo conduttore, un'interpretazione delle vicende dell'industria farmaceutica italiana, costellata di sporadiche seppur significati-