Journal of Pharmaceutical Policy and Practice

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/jppp20

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To cite this article: Kenzi Riboulet-Zemouli (2025) 1925–2025: a century of international pharmaceutical law, Journal of Pharmaceutical Policy and Practice, 18:1, 2470840, DOI: 10.1080/20523211.2025.2470840

To link to this article: https://doi.org/10.1080/20523211.2025.2470840

JOURNAL OF PHARMACEUTICAL POLICY AND PRACTICE
2025, VOL. 18, NO. 1, 2470840
https://doi.org/10.1080/20523211.2025.2470840

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LETTER TO THE EDITOR

1925–2025: a century of international pharmaceutical law

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ABSTRACT

The 1925 Brussels Pharmacopoeia Agreement and Geneva Opium Convention were foundational in shaping international pharmaceutical regulation. The former sought to standardise potent medicines, while the latter established controls over psychoactive substances. Despite differing objectives, both treaties influenced global pharmaceutical governance, contributing to modern regulatory frameworks and standards such as those of WHO or the European Pharmacopoeia. A century later, the year 2025 is witness to turbulent shifts in geopolitics and global health governance, but also revived contemporary debates on drug policy and traditional medicines. This letter revisits the seldom-documented history and impact of international pharmacy law, highlighting the relevance of these two pioneering treaties to evolving pharmaceutical governance and international health law.

ARTICLE HISTORY Received 11 February 2025; Accepted 18 February 2025

KEYWORDS Pharmacy; pharmaceutical regulations; history; international law; international relations

Some of the first executive actions taken by the incoming US administration of President Donald J. Trump in January 2025 included initiating the withdrawal of the US from WHO, and leveraging a rhetoric of pharmacological dependence-producing substances in trade-related political endeavours. From a pharmaceutical policy perspective, the timing of these actions is particularly striking. Indeed, 2025 marks the centenary of a series of milestone events in the global governance of the pharmaceutical and broader health sector.

In 1925, two pivotal treaties were adopted that regulated the same goods – potent medicinal products, at that time, essentially derived from animal, botanical, or mineral sources (Seddon, 2016) – although coming from different origins and perspectives. On 19 February 1925, the *Geneva Opium*

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Convention was signed, as a 'top-down' treaty reflecting efforts to control the global trade in pharmaceuticals associated with a potential for dependence as well as preventing their use in covert destabilisation efforts. It was rooted in the geopolitical aftermath of the 'Opium Wars,' a series of trade and military wars geared around rhetorics of opium. Conversely, the *Brussels Pharmacopoeia Agreement*, adopted on 29 September 1925, was driven by 'bottom-up' efforts from scientific societies and professional associations of pharmacists, who had long sought to standardise pharmaceutical formulations across borders. Although these treaties originated from distinct contexts with different purposes and narratives, they eventually became foundational elements of global health governance during the interwar period (Howard-Jones, 1979), and laid the ground for the WHO to embrace, at its creation, its core functions of international standardisation and regulation of the safety, purity, potency, and labelling of pharmaceutical products moving in international commerce.[1]

The legacy of these two pioneering pharmaceutical treaties and their significance – not merely as historical artefacts, but as living documents that established the foundation for international pharmaceutical law – continues to influence global health, a century after. However, the lessons learnt for and from these treaties may have been forgotten, perhaps because of their relegation to historical obscurity. The year 2025 may signify the return of geopolitical practices which were thought to have been relegated to a distant past. But 2025 is also a year of achievements for a number of workstreams started in previous years (at the regional and international level) that reflect a growing interest for revisiting trans-national pharmaceutical standards, in particular with regards to herbal and traditional pharmaceutical products, but also on some of these products associated with a potential for dependence – which sometimes overlap. In 2025, it is more than ever critical to look back at these treaties, on their centenary, to enlighten contemporary global pharmaceutical policy discussions.

Standardising potent pharmaceuticals globally: the 1925 Brussels pharmacopoeia treaty

Early efforts towards the harmonisation of medicines through pharmacopoeial monographs began in the mid-nineteenth century, driven by pharmacists concerned about the variability of medicines. In an increasingly-interconnected Europe, despite the adoption of national pharmacopoeias in most countries, significant differences in formulations persisted across borders.

[1]These core mandates are recognised in the WHO's Constitution, articles 2 and 21 (Volckringer, 1953, p. 56).

In 1864, in Strasbourg (a border city that would swing back and forth between France and Germany in the following decades), the participants at a pharmaceutical society meeting, decided to start working on standardising terminology, dosages, and composition into an 'international pharmacopoeial compendium' (WHO, 2008, p. 4). Pharmacists meetings continued, and, at the ninth such international pharmaceutical congress in 1900, the decision was taken to focus the work of harmonisation on a subset of the *materia medica*: 'potent medicaments' (officially, in French 'médicaments héroïques'). Although never precisely defined, these 'heroic' medicines referred to pharmaceutical ingredients for whom relatively-minor variations in potency could lead to significant differences in patients' clinical outcomes (Volckringer, 1953, pp. 36–74, 278–288). This choice of a smaller subset of galenical preparations served as a pretext to engage in the much needed preliminary work of harmonising weights, measures, naming conventions, and a series of connex elements not directly related to the properties of individual medicines.

The following – tenth – pharmaceutical congress was held in December 1902 in Brussels. Titled 'Conference for the Unification of the Formulae of Potent Medicaments,' pharmacists had this time been vested with diplomatic powers from their governments, allowing them to agree on a final text (Power, 1903), the 'Agreement for the Unification of the Formulae of Potent Medicaments'[2] (Table 1).

Written by pharmacists with full diplomatic powers, it took four years of textual adjustments before the Agreement could enter into force as a multilateral treaty in 19 (mostly European) countries, in December 1906.[3] The treaty harmonised the formulae of 49 medicines such as iodine or lobelia tinctures, opium, cocaine, phenol solution, etc. Consensus on harmonised formulae was disparate: some entries included directions for preparation; others, assay methods; some were merely terminological or naming clarifications. Nevertheless, the Agreement represented a first step in cross-border cooperation, as ratifying countries committed to adapting their national pharmacopoeias to the internationally-harmonised monographs, at the next revision. The Arrangement, however, failed to be appropriately embraced by governments and national pharmacopoeia commissions; as Volckringer (1953, pp. 49–52, 284–285) documents, codices such as the French or US pharmacopoeias cherry-picked different elements of the

[2]The archives can be located at: Registry files, Health and Social Questions Section, League of Nations Secretariat, League of Nations Archives, UN Library & Archives, Geneva, Switzerland; Docket R937/12B/36019. '[Seconde] Conférence internationale pour l'unification des médicaments héroïques, Bruxelles, 1925.' 2 files; in French.

[3]The archives of inter-governmental discussions have been conserved, among other, in the fonds of the *Archivo Histórico Nacional*, Madrid, Spain; Archivos Diplomáticos (Asuntos Exteriores), Docket M° _EXTERIORES_H,3185. 'Ministerio de Estado. Congresos y Conferencias: Me- (1869–1930)' In Spanish.

Table 1. Chronology of Early International Pharmaceutical Law (non-comprehensive).

	Brussels Pharmacopoeia Treaties	Geneva Drug Control Treaties
1839–1842	–	First Opium War
1856–1860	–	Second Opium War
1864	First international congress of pharmacists in Strasbourg	–
1890	–	'Convention relative to the Slave Trade and Importation into Africa of Firearms, Ammunition, and Spirituous Liquors' (Brussels)
15–20 December 1902	Conference for the Unification of the Formulae of Potent Medicaments, at the *Palais des Académies*, Brussels (Tenth international congress of pharmacists)	–
29 November 1906	Signature of the '*Arrangement International pour l'Unification de la Formule des Médicaments Héroïques*' [Agreement for the Unification of the Formulae of Potent Medicaments] (Brussels) based on the 1902 outcome document	–
29 December 1906	Entry into force of the 1906 '*Arrangement*'	–
1 December 1911–23 January 1912	–	International Opium Conference at the *Binnenhof*, The Hague.
23 January 1912	–	Signature of the 'International Opium Convention' (The Hague)
1924–1925	–	[Second] 'International Opium Conference' at the *Palais Wilson*, Geneva
19 February 1925	–	Signature of the 'Second Opium Conference Convention' (Geneva)
10–29 September 1925	IInd Conference for the Unification of the Formulae of Potent Medicaments, at the *Palais des Académies*, Brussels	–
29 September 1925	Signature of the '*Arrangement révisant l'Arrangement International pour l'Unification de la Formule des Médicaments Héroïques*' [Agreement revising the Agreement for the Unification of the Formulae of Potent Medicaments] (Brussels)	–
20 August 1929	Entry into force of the Revised '*Arrangement*'	–
1946	–	Lake Success Protocols amend the various Opium Conventions to mandate the United Nations.
1947	PIPS transferred to WHO Interim Commission. First meeting of the Expert Committee on the Unification of Pharmacopoeias (now WHO Expert Committee on Specifications for Pharmaceutical Preparations) at the *Palais des Nations*, Geneva.	–
1948	The first World Health Assembly formally institutes the Expert Committee.	–

(*Continued*)

Table 1. Continued.

	Brussels Pharmacopoeia Treaties	Geneva Drug Control Treaties
1949	–	First meeting of the Expert Committee on Habit-Forming Drugs (now WHO Expert Committee on Drug Dependence) at the *Palais des Nations*, Geneva.
1951	Publication of *Ph. Int. I*	-
20 May 1952	Signature of the 'Protocol for the termination of the Brussels Agreements for the Unification of Pharmacopoeial Formulas for Potent Drugs' (Geneva)	-
1961	-	Signature of the 'Single Convention on narcotic drugs, 1961' (New-York)
22 July 1964	Signature of the 'Convention on the Elaboration of a European Pharmacopoeia' (Strasbourg)	-
1967	Publication of *Ph. Eur. I*	-

harmonised monographs, eventually resulting in less-uniform formulae between countries.

After World War I, amidst major advancements in pharmaceutical sciences, and a booming international trade, and with the rise of the League of Nations (LoN) and its attempted normative action on public health – documented in the seminal works of Howard-Jones (1979) –, an update of the Brussels Agreement became necessary. In September 1925, a new Conference was convened at the *Palais des Académies* in Brussels. This time, participation from non-European countries was notable.[4]

The revised Agreement that was approved in 1925 (Table 1) contained 77 harmonised formulae (with additions like cannabis extract and tincture, codeine syrup, trinitrin, digitalis syrup …); it incorporated novelties such as posology standards, and created a 'Permanent International Pharmacopoeia Secretariat' (PIPS) temporarily entrusted to the Belgian Pharmacopoeia Commission but destined to become a body of the LoN. Two future technical commissions were also envisioned, to harmonise assays and methods of preparation. The Agreement entered into force in 1929 (similarly to the 1906 Agreement, it was delayed by legalese).

The desire for a proper 'international pharmacopoeia' having been in the air for decades, the pharmacists who had been delegated to negotiate the text were convinced that the progressive adoption of the Agreement's monographs in national pharmacopoeias would this time *de facto* 'secure the principal object of an international pharmacopoeia'.[5] Yet, the Agreement did not mention the words '*international pharmacopoeia*.' Instead, it recommended appending the

[4]e.g., Australia, Egypt, Haiti, Japan, Peru, South Africa, Türkiye, etc.
[5]This sentence is mentioned in a footnote of the U.S. Department of State's official treaty repository (1969, Vol. 1, Multilateral treaties, 1776–1917, p. 568).

initials '*P. I.*' (for '*protocole international*') to the right of the titles of harmonised national monographs. As the adoption of the 1925 harmonised monographs was substantially higher than for the 1902 Agreement, and as national codices added '*P. I.*' to a number of their monographs, the acronym became widely misinterpreted as meaning '*Pharmacopoeia Internationalis*'.[6]

Although the monographs harmonised in 1925 received greater acceptance and transliteration into national pharmacopoeias, the overall success of both 1902 and 1925 Agreements was relatively low.

After World War II: drug standardisation from Brussels to Geneva

The LoN' efforts to reclaim the mandate of the PIPS were only realised in the aftermath of World War II. As early as 1947, the Interim Commission of the WHO reached out to the Belgian government to incorporate the PIPS. In September that year, an 'Expert Committee on the Unification of Pharmacopoeias' met at Geneva's *Palais des Nations*, using the Brussels 1925 Agreement as a basis for its work, albeit deleting about half of its entries (Volckringer, 1953, pp. 55–60, 282–290).[7] This marked a certain alteration in the project's scope, which departed from the 1902/1925 focus on 'potent medicaments,' shifting towards a broader selection of pharmaceutical substances without explicit consideration of their strength, potency, or pharmacology. In July 1948, the first World Health Assembly formally instituted the Expert Committee, later renamed 'Expert Committee on the International Pharmacopoeia'.[8]

In 1951, the Committee released the first volume of the 'International Pharmacopeia' (*Ph. Int.*), finally. The following year, governments resolved to discontinue the 'generally obsolete' 1925 Brussels Agreement, encouraging its replacement by *Ph. Int.*[9] However, taking stock of the disparate adoption of the previous harmonised monographs in national pharmacopoeias, *Ph. Int.* also shifted away from the binding treaty format associated with Brussels 1902/1925 treaties, towards adopting a model of voluntary standards aimed at supplementing national pharmacopoeias rather than replacing them.

The binding treaty format, however, would return. In 1964, the 'Convention on the Elaboration of a European Pharmacopoeia' revitalised this legal principle, by establishing the European Pharmacopoeia (*Ph. Eur.*)[10] as a

[6]Interestingly, some national monographs even miswrote the acronym, using '*Ph. I.*' or even '*F. I.*' (Spanish for '*Farmacopea Internacional*').

[7]The minutes of this session, containing the list of deleted entries, can be consulted at: Archives WHO1, World Health Organisation Archives, Geneva, Switzerland; Docket 758.4.1. 'Unification of Pharmacopoeias Committee. Sessions: 1st Session, Geneva, October 1947.' French and English.

[8]It is today known as the 'WHO Expert Committee on Specifications for Pharmaceutical Preparations' (WHO, 2008).

[9]'Protocol for the Termination of the Brussels Agreements for the Unification of Pharmacopoeial Formulas for Potent Drugs' (1955).

[10]Established in 1964, the *Ph. Eur.* is based in Strasbourg, the city where the first international pharmaceutical meeting was held in 1864.

binding framework promoting the gradual adoption of harmonised monographs across member States.

Regulating psychoactive pharmaceuticals globally: the 1925 Geneva drug control treaty

While the Brussels Agreements focused on uniformising standards for pharmaceuticals, the Opium Conventions addressed a different but equally critical aspect of potent medicaments: the control of their international trade.

The first multilateral treaty controlling a pharmaceutical substance with potential for harmful effects was the 'Convention relative to the Slave Trade and Importation into Africa of Firearms, Ammunition, and Spirituous Liquors' of 1890 which regulated alcohol sales in colonial West Africa (Bruun et al., 1975, pp. 9–13; Seddon, 2016). However, it is the 'International Opium Convention' concluded at the Hague in 1912 that is remembered as the starting point for international drug control law (Pietschmann, 2007). McAllister (2000, p. 38) points at the 'cultural preferences and manifest power of the western industrialized nations' in determining that certain psychoactive drugs – chiefly alcohol – would escape from the regulatory environment of oversight over pharmaceutically-active substances.

The 1912 International Opium Convention was also embedded in its era of colonial geopolitics, resulting from the aftermath of the successive 'Opium Wars' which had opposed China to various Western countries in the nineteenth century (Pietschmann, 2007). The treaty aimed at 'the gradual suppression of the abuse of opium, morphine, and cocaine as also of the drugs prepared or derived from these substances.' In essence, it mandated ratifying nations to respect other countries' bans on the imports of these substances – then an integral part of the *materia medica* in many countries –, while regulating trade between countries allowing it. Yet, the Convention 'urged much but required little' (McAllister, 2000, p. 39) reflecting the challenge in balancing restrictions and therapeutic access; it did not gain traction.

The 'Paris Peace Treaties' which followed World War I changed the landscape. Not only did they require ratification of the 1912 Opium Convention, but they instituted the LoN as the entity entrusted with coordinating early drug control efforts (Howard-Jones, 1979).

Once in charge, the LoN undertook to adopt a series of additional drug control treaties in the inter-war period (Rexed et al., 1984). Among these, the 1925 [Second] 'International Opium Convention' concluded at the *Palais Wilson* in Geneva, is paramount. Updating and replacing the 1912 Hague treaty, it established a much more narrow oversight and regulatory framework for every stage of the production and distribution of controlled pharmaceuticals, and extended control to cannabis medicines. The Second International Opium Convention also required statistical returns by

governments on the trade and use of these drugs to a newly-established international body, the 'Permanent Central Opium Board'.[11]

Whereas pharmacists were the principal drafters of the Brussels Pharmacopoeia Agreements, their role in the Geneva negotiations was markedly different. Unlike for Brussels' pharmacopoeia treaties, the Geneva drug control negotiations were led by politicians and diplomats. Delegations did incorporate a number of health experts as advisors, but very few were pharmacists. Ahead of the adoption of the 1925 Geneva Opium Convention, an international pharmaceutical congress had even raised concerns that certain provisions might 'prove a source of worry and annoyance and hinder [pharmacists] in their practice' (cited by Bruun et al., 1975, p. 153).

After World War II: drug control from Geneva to Vienna

In 1946, the 1925 Opium Convention and other pre-War drug control treaties were brought under the auspices of the United Nations (UN), which established in Geneva a 'Commission on narcotic drugs' (CND).[12] Contrarily to the WHO's Pharmacopoeia Committee composed mostly by pharmacists who cut down the list of harmonised drugs, the CND was attended by diplomats who undertook to expand the scope of the Opium treaties beyond the three traditional medicinal plants they originally controlled (cannabis, coca, and opium poppy) and their derived galenical products. In 1948, the Paris Protocol extended international drug control to potentially all drugs having a 'similar' potential for dependence than cannabis, cocaine, or opium (Rexed et al., 1984, p. 16).

Finally, in 1961, the various drug control treaties and the post-War Protocol were discontinued and replaced by a newer, comprehensive 'Single Convention on narcotic drugs.' It was later supplemented by the 1971 'Convention on psychotropic substances' concluded in Vienna, Austria. These treaties, which remain the bases for international drug control law in 2025, designate the WHO as 'the only treaty body with a mandate to carry out medical and scientific assessment of substances' (WHO, 2018), determining their inclusion or exclusion from international control via its Expert Committee on Drug Dependence. In doing so, decision-making on the list of internationally-controlled medicines was finally handed to scientists – mostly pharmacologists –, as it had always been the case for the list of internationally-harmonised monographs.

Conclusion

The 1925 Brussels Pharmacopoeia Agreement represented the first effective attempt at harmonising pharmaceutical standards for potent drugs across

[11]It was replaced in 1961 by the International Narcotics Control Board (INCB), still active today.
[12]The CND relocated to the Vienna UN headquarters at their opening in 1979, soon followed by the UN drug control secretariat and the INCB (McAllister, 2000).

borders, laying the ground for the later global approach to drug safety and efficacy. The 1925 Geneva Opium Convention, similarly, contributed to international health governance by addressing the trade in potent drugs on a global scale. Together, these two century-old treaties shaped an international legal framework which was, for the first time in human history, fundamentally centred around pharmaceuticals.

A century after their inception, these treaties continue to shape governance, standards, and trade, with profound implications for physicians, pharmacists, and patients. Despite the passage of time, the objective of these treaties are still being pursued. The global harmonisation of pharmacopoeias remains an ongoing endeavour, and promising steps forward continue to be taken on the *Brussels side* of global pharmaceutical regulation: besides continued enhancements of *Ph. Int.* and the internationalisation of *Ph. Eur.*,[13] the year 2025 will see the launch of the 2025–2032 Global Strategy for Traditional Medicine (planned for adoption during the 78th World Health Assembly, in May), the consolidation of the group of countries 'Friends of Traditional Medicine' with a common political agenda, and the 2nd WHO Global Traditional Medicine Summit, in December (WHO, 2024).

On the *Geneva side*, the appropriateness and modalities of restrictions and regulations applied to pharmaceutical products with potential for dependence (and/or used outside of the medical context) also continue to be debated. This is particularly the case for drugs associated with traditional pharmaceutical practices or part of Indigenous medicine, such as coca leaf or cannabis. 1925-like debates remain on the agenda of contemporary health regulatory institutions, at the national level as well as internationally: in 2019, the WHO's Expert Committee on Drug Dependence assessed cannabis and its medical uses[14]; a similar exercise is planned for coca leaf in 2025.

On the other hand, the ongoing 'opioid crisis' in Northern America has led to questioning the system of international cooperation established by the Opium Conventions, as contemporary approaches to geopolitics brought in by the incoming US administration seem to be evocative of the period of the Opium Wars, rather than of the international cooperation brought in by the 1925 Conventions.

Nowadays, international trade in pharmaceuticals is regulated under a myriad of other treaties – trade agreements, intellectual property law, anti-counterfeit provisions, but also treaties on agriculture, biodiversity, bioethics, biopiracy, and access and benefit-sharing for genetic resources and associated traditional knowledge – but for how long? As we navigate a complex era of evolving public health and geopolitical challenges, it is worth remembering the history of 'international pharmaceutical law,' recognising its

[13]There are 31 non-European observer countries as of 2025.
[14]A monograph of cannabis was recently added to *Ph. Eur.*

specificity and convoluted history, to better address its legacy within the current global health governance. The lessons learnt from the international cooperation developed via these treaties can guide present and future efforts; by revisiting these historical precedents, we can better address current challenges and strive collaboratively for more sustainable, ethical, and effective pharmaceutical policies.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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