

## BRIEF OUTLINE OF THE EVOLUTION OF PHARMACOPOEIA IN ARGENTINA

By Ariadna Matilde VIGLIONE

The need to set regulations for the prescription and preparation as well as for the formulation and dosing of medicines gave rise to official pharmacopoeias, legal instruments created to regulate relations among the parties involved in the art of curing diseases.

It has become usual to refer to Pharmacopoeia as the "Bible of the Pharmacist".<sup>2</sup> Like most metaphors, this one reflects only part of the truth. The usefulness of pharmacopoeia is determined by the regular changes it requires in order to catch up with the progress of the basic sciences. Thus, frequent revisions are necessary.

The term "Pharmacopoeia" was coined in 1573 to refer to the official pharmaceutical practices (Pharmacopoeia Augustana). This term was used at the beginning for all kinds of formularies and gradually evolved to the official term to denote a legal instrument.

France was the first nation to use the word "Codees" to designate the Pharmacopoeia, which was meant to indicate the mandatory nature of this kind of instruments.

Having a Pharmacopoeia gradually became a matter of national interest in many countries. Approximately 35 countries have their own Pharmacopoeia and many others are expected to follow. In America only 7 countries have their own national Pharmacopoeia: **Argentina** (eight editions: 1898; 1921; 1943; 1956; 1966; 1978; 2003 y 2008), **Brasil**<sup>3</sup> (five editions: 1929; 1959, 1976, 1988-2005 y 2010), **Chile** (four editions: 1889; 1905; 1933; 1942)<sup>4</sup>, **United States of América, México**<sup>5</sup> (thirteen editions: 1846; 1874; 1884; 1896; 1904; 1930; 1952; 1962; 1974; 1988; 6th edition in 1994; 7th edition in 2000; 8th edition in 2004 with the addition of the medical device appendix in 2006 and the ninth 2008 edition with Homeopathic Pharamacopoeia, 2nd 2007 edition, both effective), **Paraguay** (1939) and **Venezuela** (two editions: 1856 and 1942). Other countries have adopted the French, the US or the British Pharmacopoeia.

A Pharmacopoeia or Codex Medicamentarios is the official collection that contains the most usual types of drugs adopted by experience at the time of their appearance and the different preparations and medicines that have proven useful for Medicine and Pharmacy in their different aspects, including origin, nomenclature, preparation, identification, purity, value, doses and other conditions that ensure the quality and consistency of their properties.

Since the time of the Spanish Colony to date the Argentine Republic applied the Army Pharmacopoeia and other books that contained the most broadly used formulas during the time of the Colony; the Spanish Pharmacopoeia during the time of the Viceroyalty and the French Pharmacopoeia until the end of the 19th Century since it

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1 Urdang, G; 1952 Evoluci'on de las Farmacopeas

2 Imbessi, A 1964 INDEX plantarum

3 Consult with Dr. Prof Geraldo Carlini, Sao Paulo University

4 Consult with Dra. Ruth Pollemann Conception University of Chile

5 [WWW.farmacopeamexicana.gov.mx](http://WWW.farmacopeamexicana.gov.mx)

was more advanced for the time and also because most Argentine professionals were trained in France. Since the end of the 19th Century the National Argentine Pharmacopoeia has been used with seven official editions.

It has been over a century since the country has ceased to be ruled by foreign codes.

Section 28, Title III of the Decree of April 9<sup>th</sup> 1822 signed by Governor Dr. Martin Rodriguez and his Minister Bernardino Rivadavia, titled Of Pharmacy and related professions, which regulated Medicine, Pharmacy and allied disciplines and also created the Medicine and Pharmacy Tribunal read as follows:

*“A professor who prescribes a formula that is not explained in the Spanish Pharmacopoeia, IV edition shall describe the way of preparation of the medicine as part of the prescription; otherwise the prescription will not be filled by any pharmacist”.*

The Spanish Pharmacopoeia ruled until shortly after the suppression of the Court of Medicine. The Hygiene Board that succeeded it was created by Decree of the Buenos Aires Government in 1852. The Spanish Code was very rarely used and for many years was only opened by beginner Pharmacists to find a purgative mixture or any similar formula which would rarely be prescribed by a doctor due to the reputation it had as D.Demarchi states in the Pharmaceutical Review of January 1858:

*“It was no longer sufficient to satisfy the needs of our pharmacy as was stated by the members of the National Hygiene Board in Section 14, Title V which read: “the Paris Pharmacopoeia will be applied for the composition of official medicines until a Buenos Aires Pharmacopoeia is developed; however, all other prescriptions will be filled applying other Pharmacopoeias”.*

The Law regulating the practice of Medicine, Pharmacy and other disciplines related to the art of curing diseases approved by the Legislature of the Province of Buenos Aires on July 16, 1877 and passed on July 18<sup>th</sup> the same year, “Practice of Pharmacy”, includes the following articles in chapter 3 :

*“15...will always have the following simple substances and official medicines commonly used and well known in medical practice”.*

*Said substances and medicines that are part of the Petition are those that are marked in the official pharmacopoeia with an asterisk. [The pharmacist] will always keep a copy of said Pharmacopoeia with the official Annexes, if any...*

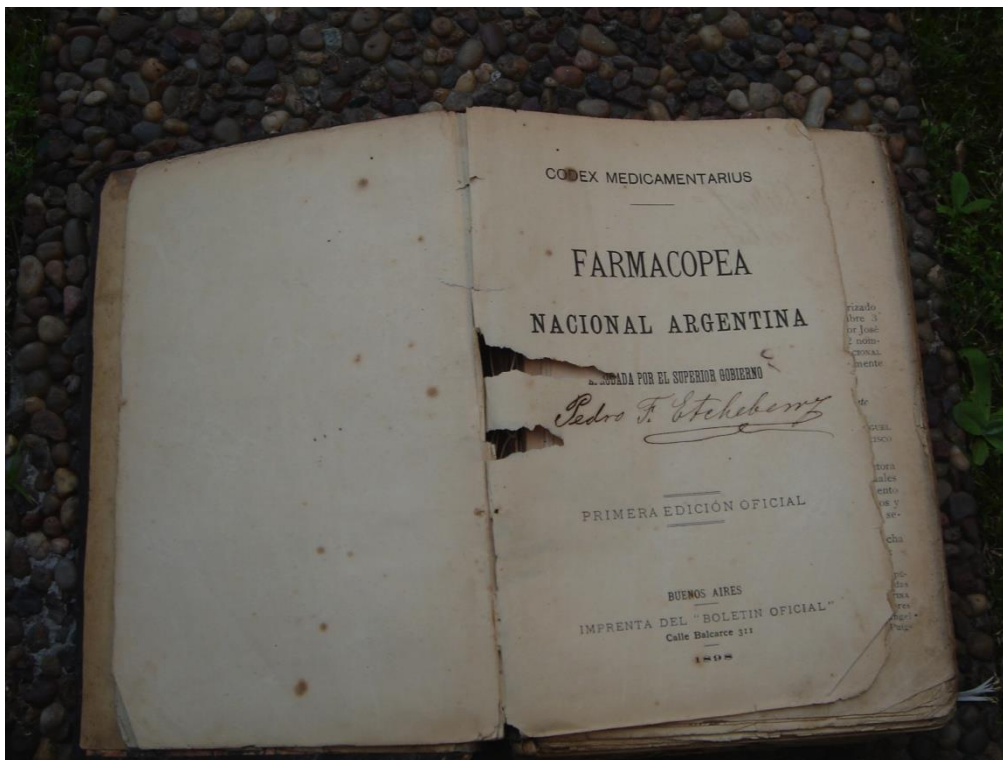
*“16: For the composition of official medications the formulas of the French Pharmacopoeia, edition 1866 will be applied until a Buenos Aires Pharmacopoeia is elaborated. However, the pharmacist may fill the prescription applying any other Pharmacopoeia as long as the physician so indicates in the prescription”.*

Since its foundation in 1856, the BUENOS AIRES PHARMACEUTICAL ASSOCIATION, which later evolved to become the NATIONAL ACADEMY OF PHARMACY AND BIOCHEMISTRY, made great efforts to produce a national Pharmacopoeia and submitted two drafts elaborated by Dr. Estanislao ZUBIETA in

1889, and one by Miguel PUIGGARI in 1881, which were used by the government for decision-making purposes.

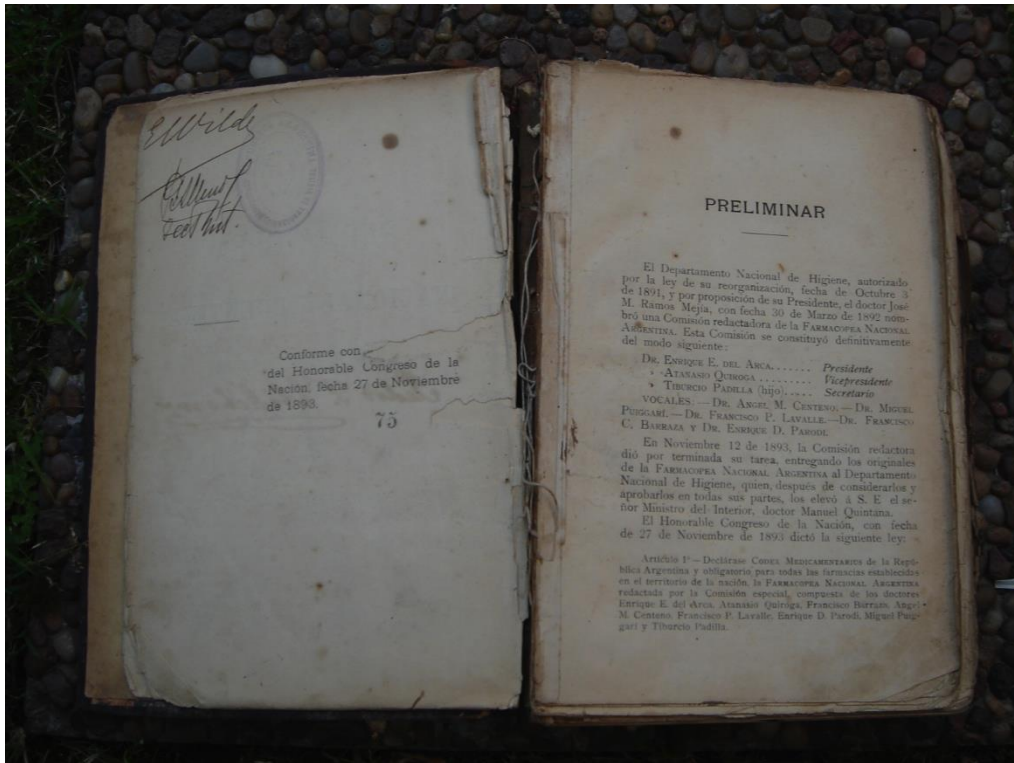
The **First Edition**, was made mandatory for all pharmacies in the country by Law N° 3041 dated December 1, 1893 and made effective by a Decree dated October 16, 1899 once the official edition elaborated by the National Hygiene Board approved the official edition.<sup>6</sup>

The need to maintain this scientific and legal instrument updated so that it can fully respond to the constant advances in therapies led the National Executive Power to establish a regular fortnightly review as provided by Section 8 of the Decree dated September 18, 1906 which regulated Law N° 4687 on the Practice of Pharmacy.



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<sup>6</sup> Pharmacopeia, First edition official impression



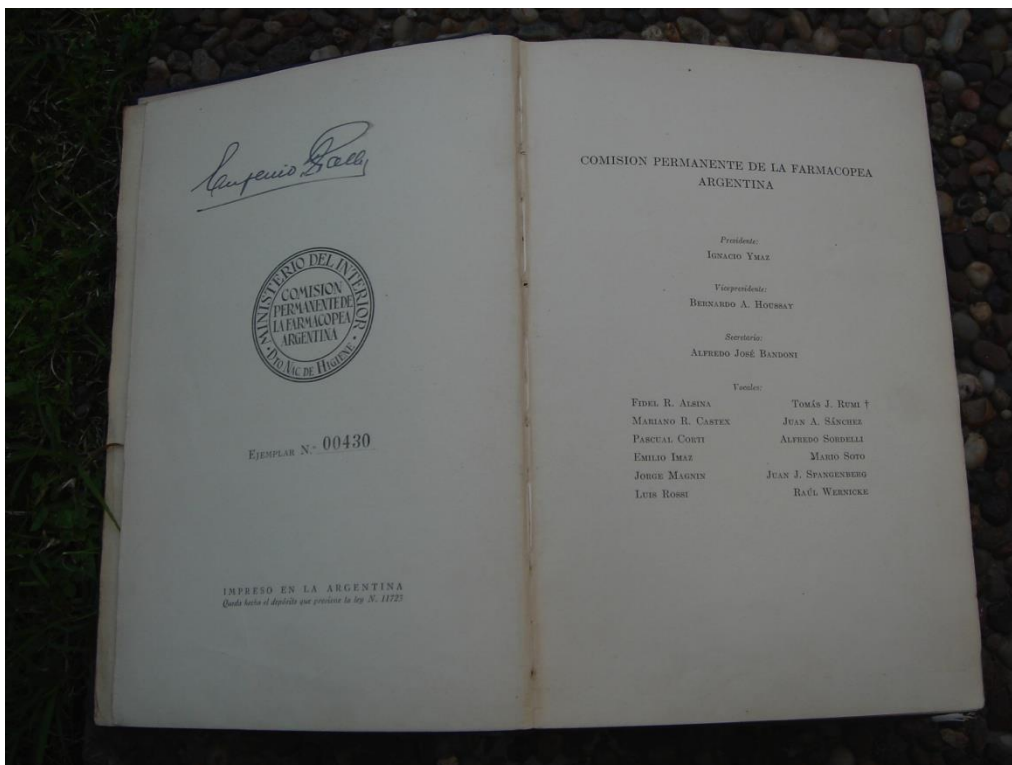
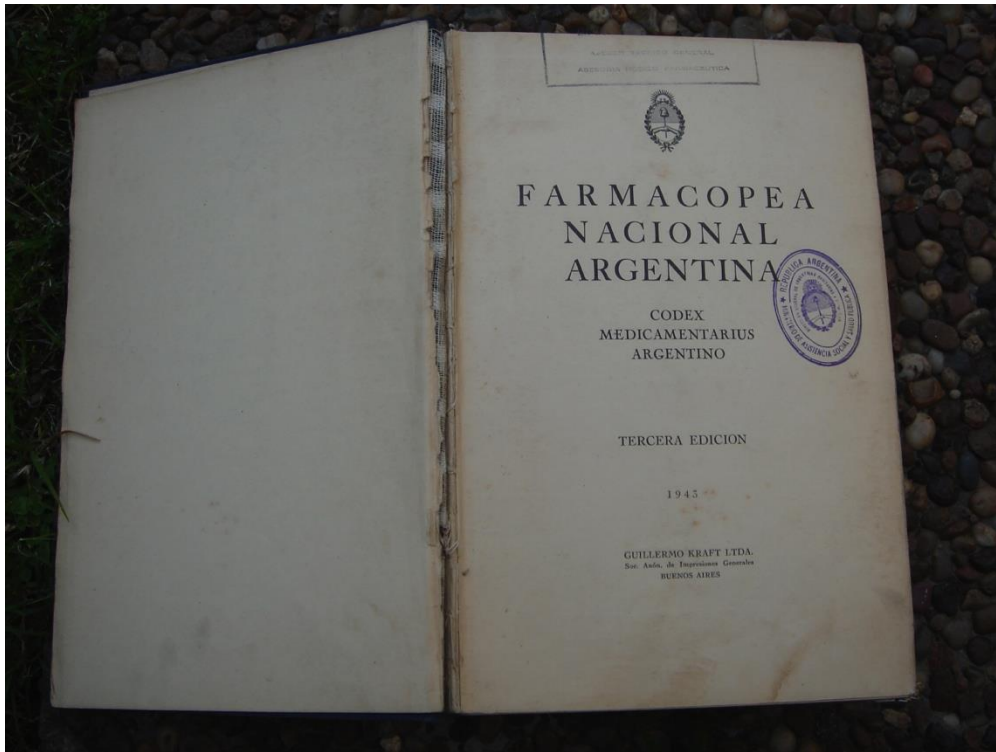
The **Second Edition** approved by Law 10.983 dated September 30, 1919, became effective on January 1, 1923.<sup>7</sup>

A reprint of the second 1921 edition was authorized in 1927 and published in 1928 wrongly identified as the third edition.

The **Third Edition** was authorized on September 29, 1941, ratified by Law 12.728 and became effective in 1943.<sup>8</sup>

<sup>7</sup> Pharmacoepia, Second edition official impression

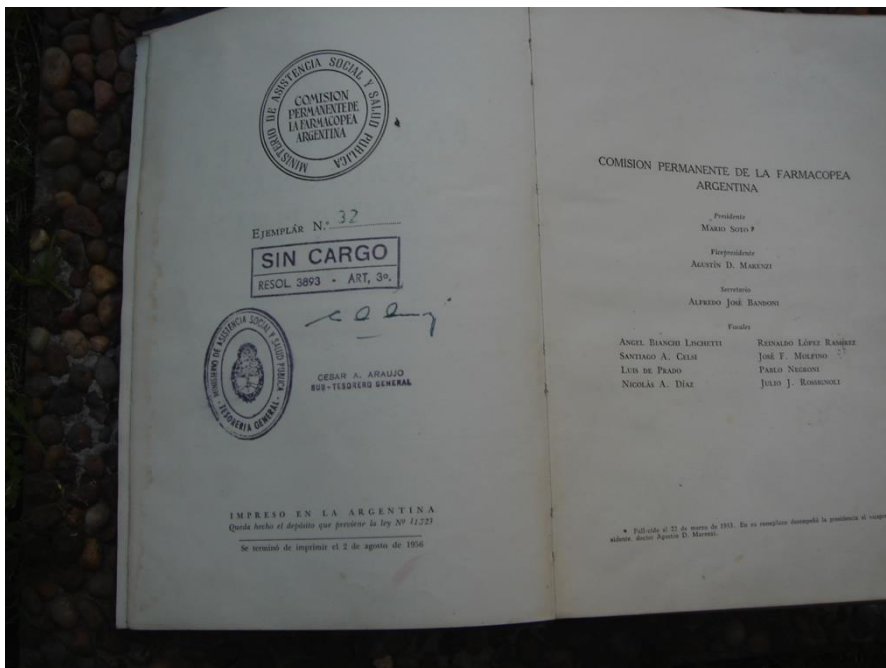
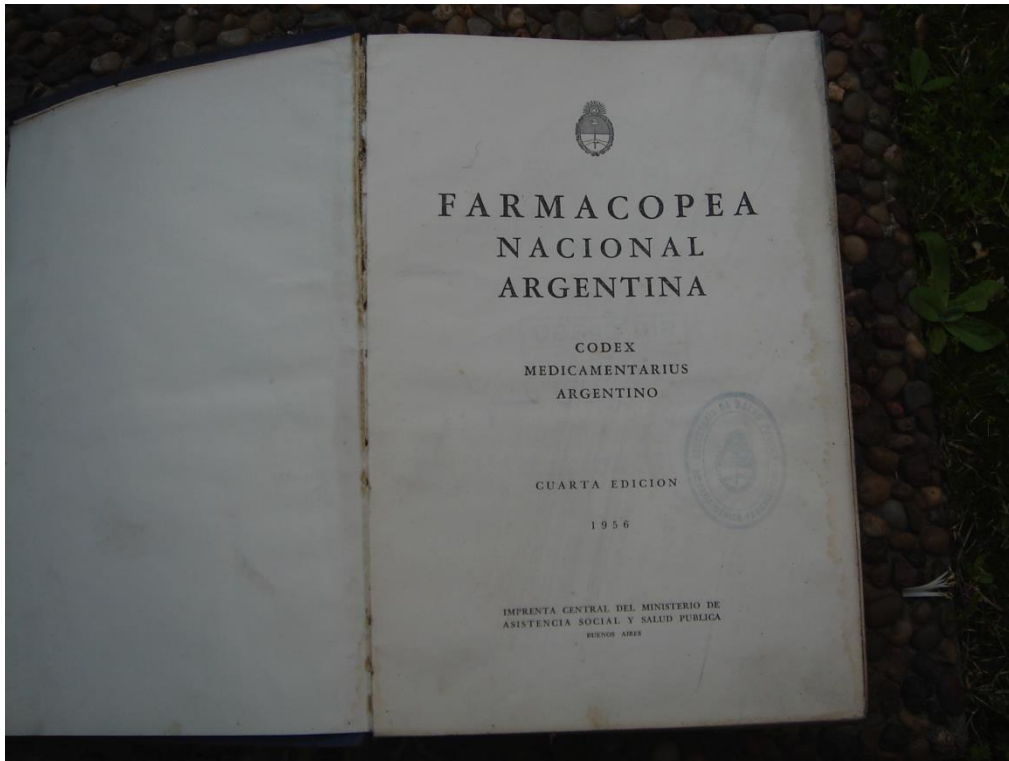
<sup>8</sup> Pharmacoepia, Third edition official impression



The **Fourth Edition** became effective on June 1, 1957 and was ratified by Executive Power Decree N° 4944 dated December 12, 1955.<sup>9</sup>

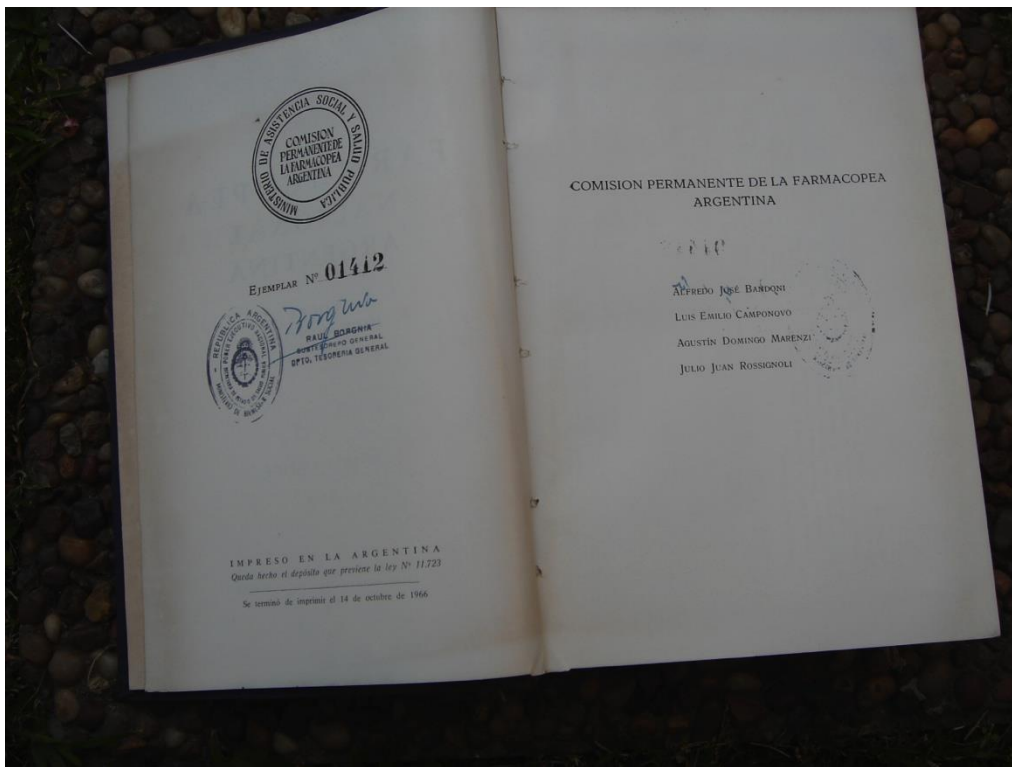
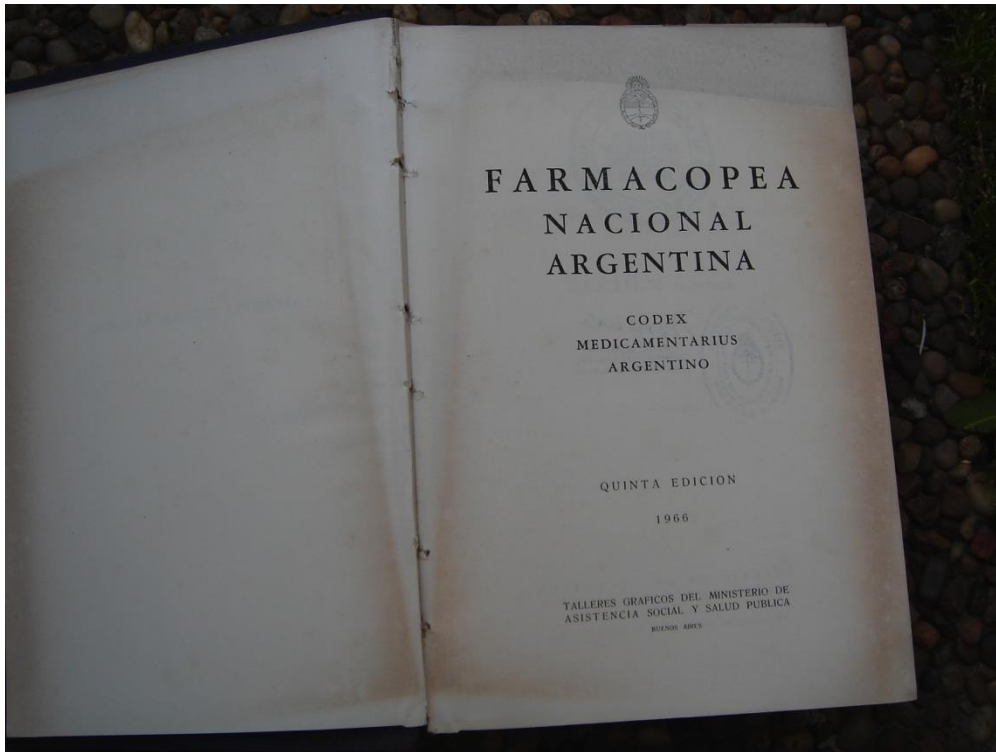
<sup>9</sup> Pharmacopeia, Fourth edition official impression





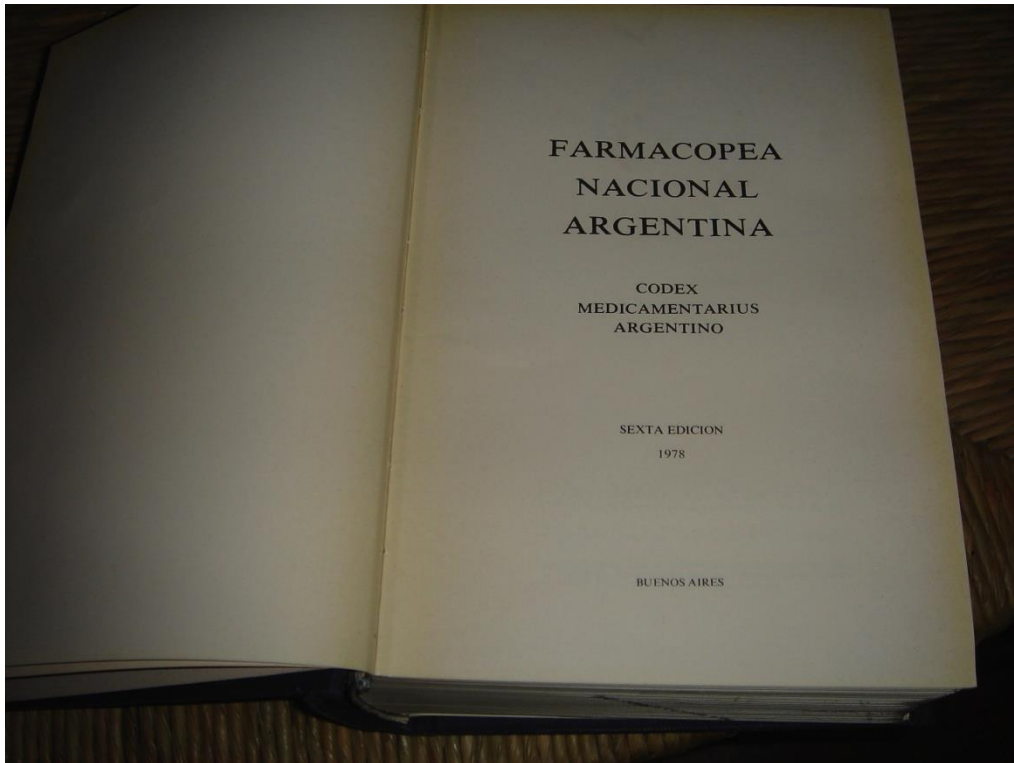
The **Fifth Edition** became effective on June 1, 1968 by Resolution N° 995 dated April 4th, 1967. It was ratified by Law 16.969 of October 4, 1966,<sup>10</sup> and

<sup>10</sup> Pharmacopeia, Fifth edition official impression



The **Sixth Edition** became effective on March 1, 1979 by Resolution N° 418 dated February 21, 1979. It was ratified by Law 21.885 and is effective to date.<sup>11</sup>

<sup>11</sup> Pharmacopeia, Sixth edition official impression



A permanent consultation and update system was designed for the new Pharmacopoeia edition which allows for the participation of the public involved in the use of the medicines. The new structure of the Standing Committee comprises new members and 21 specialized subcommittees in different areas. Each subcommittee is coordinated by a representative of INAME. The members of these subcommittees are appointed by universities and the pharmaceutical industry and their work is *pro bono*. The subcommittees comprise over 300 professionals and faculty from throughout the country. Each member receives individually the different sections of the Pharmacopoeia for evaluation and their suggestions are submitted to the Standing Committee Secretariat. Once the different suggestions have reached consensus, the text is posted in the Internet in the Pharmacopoeia site with unlimited access.

The publication of the monographies in the Internet seeks the purpose of providing for a public consultation period during which any stakeholder may submit an opinion and send their suggestions to the Pharmacopoeia Standing Committee.

The web page of the Argentine Pharmacopoeia is part of the ANMAT (National Food, Drug and Medical Technology Administration) site and users can access through the main page. To date over 200 drug and excipient monographies have been posted.

According to the initially proposed schedule, the seventh edition of Argentine Pharmacopoeia became effective in 2001 and continued with the publication of one supplement per year during four years in order to publish the eighth edition in 2004.

Since medicines have become a product of the pharmaceutical industry, the Pharmacopoeias have turned into real quality standard codes which are indispensable to standardize the pharmaceutical market and provide for quality conditions so that they can be legally distributed in the market, safeguarding the public health.



In this respect, it is important to highlight that since the creation of ANMAT and according to the adopted management supervision model, growing emphasis is laid on compliance with Good Manufacturing and Surveillance Practices, requiring the gradual adaptation to the standards established by the World Health Organization (OMS), a fundamental starting point to safeguard the pharmaceutical quality of medicines.

In the Prologue to the **Seventh edition**<sup>12</sup> (whose first volume was ratified by Decree N 202/2003 dated June 12, 2003), the then Minister of Health wrote:

*“The year 2002 was particularly harsh in Argentina. The crisis was generalized and health was no exception. Long standing structural problems combined with the political situation had a deleterious effect on the economic, social and health conditions of our population...”*

*The change requires operating on several aspects simultaneously. The promotion of the generic names of medicines is without any doubt a strategic tool. The purpose and scope of such strategy is simple and transparent: it is a matter of separating the clinical act of prescribing a medication from the trade name of a product and the underlying commercial interests.*

*Leaving aside the issue of the trade name, other issues related to the quality of medicines need to be discussed. Such discussion will necessarily be biased if the decision on a prescription is marketing oriented.*

*And in this respect the State plays a fundamental role. It is in this context that this work acquires its true value and dimension. It is a fundamental contribution to promote the continuous improvement of the quality of all medicines.*

*Once again, I urge you and other fellow citizens to renew the commitment with a public policy that guarantees access to health to all Argentine citizens”.*

*Dr. Ginés González García  
Minister of Health of Argentina*

The **EDITION** finished to publish in 2013,<sup>13</sup> with four volumes published in the Internet (still pending approval by the Congress) is posted in PDF format in the Web site: [www.Farmacopea Nacional Argentina.gov.ar](http://www.Farmacopea Nacional Argentina.gov.ar)

*“A first volume was published in 2003 with the purpose of completing the Seventh Edition on a regular annual basis with the other three volumes. Although the goal was achieved, considering the time lapsed, the changes that have taken place in the technical teams of the Health Authority and having the ANMAT incorporated the Pharmaceutical Inspector Cooperation Scheme), that it is a National Regulatory Medication Authority acting as a Reference of the Panamerican Health Organization and considering the scientific and medical*

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<sup>12</sup> Pharmacopeia, Seventh edition official impression

<sup>13</sup> Pharmacopeia Seventh edition, official impression and web site [www.Farmacopea Nacional Argentina.gov.ar](http://www.Farmacopea Nacional Argentina.gov.ar) Disposición ANMAT 6501/2013 del 5/11/ 2013, publica en el web site [www.ANMAT.gov.ar](http://www.ANMAT.gov.ar)

*progress that has taken place, we have deemed it convenient to present this as a New Edition".*

Pharmacist and Biochemist Héctor Giuliani  
Executive Director

Many distinguished Argentine researchers, scientists and faculty have been involved in the elaboration of subsequent editions of our Pharmacopoeia, proving that qualified human resources are necessary to materialize such an important work and proving once again that the "***Bible of pharmacists***" remains alive and updated, incorporating all the technological resources to keep up to the pace of science and in order to provide professionals with an appropriate level of security and a better service for the benefit of all patients.

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