



GUEST CONTRIBUTION

A HISTORICAL PERSPECTIVE ON PHARMACOPOEIA

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Drugs were doubtless developed when man's life started on Earth. All beings, and humans too have always sought ways to overcome their ailments and diseases. Humans have tried to improve their living conditions and lengthen their life using various objects from the wildlife that once, intuitively and empirically, improved their health or at least palliated their ailments. Perhaps the origin of the pharmacopoeias, could be the set of useful remedies for curing human illnesses that have come through Egyptian, Mesopotamian, Chinese, Indian, Greek, Roman, Islamic and Christian cultures and that throughout history have been improving and adapting.

The same fact happened in Mexico and Peru. Before Islam arrived, there was no professional division between physicians and pharmacists. With more or less technical and scientific training, the same individual practised both activities. In the ninth century in Baghdad, the separation of tasks was initiated: physicians were responsible for diagnosis and prognosis of diseases and pharmacists were responsible for the preparation of medicines. Later, over time, the classic medical order given to the pharmacist would be expressed in recipes or prescriptions: 'Fiat secundum artem' or 'Dp/DPS' (Dispense). Once this separation occurred, the first books aimed at physicians and pharmacists appeared in order to establish their duties. These books were intended to expedite the prescriptive functions to physicians and the preparation of remedies to pharmacists, so that the medication given to patients of a certain territory was similar. Thus, we might consider the term pharmacopoeia as 'the book of drugs, the book of health'.

During the European Christian Middle Ages, the authentic legal separation between Medicine and Pharmacy took place by prohibiting the exercise of both professions at the same time, but it was not a divorce. This circumstance happened during the Reign of Federico II, King of Sicily, in 1240, considering this fact, therefore, as the 'Magna Carta of

Pharmacy'. The above mentioned separation began in Italy, continued in France and Spain, and then it was extended throughout the rest of Europe. Since then, as required by law and generally accepted, the pharmacopoeias have arisen in their modern conception. Consequently, these books are intended to specify the preparation of medicines for an essential and mandatory use for physicians who prescribe and pharmacists who prepare the medicines within a certain geopolitical unit. Pharmacopoeias are, therefore, official books, primarily intended for physicians and pharmacists; for this reason, they are part of the history of science and culture as they are related to daily life, illness and the humans' desires to prevent diseases and preserve their health. In consequence, it could be argued that pharmacopoeias are an essential part of the history of humanity, a text whose mission is to establish the characteristics of drugs and has legal force or has been accepted in order to harmonise the professional practice in a given territory. The first official pharmacopoeia was the Ricettario Fiorentino, whose full name was 'Nuovo receptario composto dal famosissimo Chollegio degli eximii Dottori della Arte et Medicina della ínclita ciptá di Firenze' printed in Florence in 1498, whose mission was to try to eliminate the large differences in this city, according to the different ways of preparing medicines. In that 'ricettario' three parts can be distinguished: one aimed at identifying samples, other for compounds and the last one at establishing certain forms of complicated processing; this pharmacopoeia also included a section for weights, measures and synonyms. It was written by physicians, and allowed to facilitate their relationships with pharmacists. Physicians prescribed the medication they wanted for their patients and pharmacists perfectly knew how to prepare it. In conclusion, this book simplified everything. Thus, the same medicine would receive the same name for being prepared in a pre-established way.

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Then appeared the Catalan Concordias: Concordia Apothecariurum Barchinonensium, published in Barcelona in 1511; Concordia Pharmacopoliarum Barchinonensium, 1535; Concordias of Saragossa, Concordia Aromatariorum civitatis Cesarauguste, 1546 and 1553, Dispensatorium Pharmacopolarum, 1546, and then the one of Mantua (1559), Cologne (1565), Vienna (1570), Montpellier (1579), Rome (1583), Ferrara (1595).

In the Iberian Peninsula, the first pharmacopoeias appeared in the Kingdom of Aragon, territory where trade associations were stronger, the exercise of pharmacists was better established and these professionals were considered as people of influence. In Valencia the pharmacopoeias *Officina Medicamentorum* were published in 1601 and 1693, and after them, the first Spanish Pharmacopoeia to be enforced for the whole of Spain, the *Pharmacopoeia matritensis*, was published in Madrid in 1739.

The analysis and control of drugs is an area of knowledge of prime importance both in the development of new drugs, and in the control of the existing ones. The need to ensure the effectiveness, safety and quality of medicines requires verification, monitoring and control systems, increasingly becoming sophisticated and also subject to a rigorous and varying regulations, according to the scientific advances. Hilarión, a famous pharmacist, already said in the Madrid noted zarzuela called 'La Verbena de la Paloma' by Tomás Bretón, that sciences advanced in an outrageous way.

The knowledge of the importance of analytical methods presented in the lifecycle of a drug is as necessary an approach as knowledge about the different stages of drug development. In this sense, analytical techniques play a crucial role in all stages of a drug, in other words, these stages include: the research, the development of a new compound, the study of the suitable pharmaceutical form and the production and control as well as the knowledge of the state of conservation.

One of the most important uses of instrumental techniques in Pharmacy is undoubtedly the qualitative and quantitative determination of compounds which act as active ingredients or excipients of medicines. There are numerous methods that are regularly used for this purpose; being necessary to know the possibilities and limitations of each of them in order to select the most suitable method for the analysis that must be performed. It is sometimes possible to combine two or more techniques to solve specific problems.

The term ICH strongly arises (The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use). This Conference was originated in Europe, Japan and the United States, as a result of various events occurring in the decades prior to 1970. ICH comes together in the 1980s, in the European Union, its birth being regarded in Brussels in April 1990. The objectives of ICH are mainly to regulate the various technical and scientific methods used in Europe, Japan and USA, as regards medicines.