AN OVERVIEW ON PHARMACOPOEIAS IN THE WORLD AND MONOGRAPH ELABORATION TECHNIQUES

ABSTRACT

Pharmacopoeia are official sources that contain national and international rules that must be complied with legally and scientifically regarding substances, materials, drugs, devices and methods used in pharmaceutical field and pharmaceutical production.The monographs are consisted of general titles such as definition, production, characters, identification, tests, assay, storage, labelling and impurities. The World Health Organization states that sixty eight different pharmacopoeia continue to be used effectively in fiftysix countries around the world. In this review information about national and international wold pharmacopoeias, structure and general content of pharmacopoeias, and monograph elaboration techniques are given.

Keywords: Pharmacopoeia, international pharmacopoeia, national pharmacopoeia, general monograph, national monograph,monograph elaboration.

INTRODUCTION

A pharmacopoeia, pharmacopeia, or pharmacopoea, is a scientific legal binding reference book, prepared by a national or regional authority, of standards and quality specifications for medicines used in that country or region [1]. Pharmacopoeia are official books containing national and international rules and methods that must be followed legally and scientifically, including qualitative and quantitative analysis methods of active substances and excipients used in pharmaceutical production. Monographsrefer to the pharmacopoeia section that define the definition, content, morphological (appearance), physicochemical (such as solubility, melting and boiling point) and biological (biological activity and the definition) properties, recognition-diagnostic analysis, quantification, packaging and storage conditions of chemical/biological/biotechnological active and auxiliary substances, herbal/animal drugs and preparations finished products or medicinal products.Pharmacopoeia maintains public health and quality of drugs by combining the procedures recommended for analysis and specifications for the determination of pharmaceuticals, excipients and dosage forms, usually consisting of general sections (tests, methods and general requirements) and special monographs. Pharmaceutical analysis represents a platform through which state-of-the-art research can affect the quality, safety and efficacy of medicines directly by pharmacopoeial application of scientific results into everyday practice [2].

The World Health Organization (WHO) states that sixty-eight different pharmacopoeia continue to be used effectively in fifty-six countries around the world and in the European Union, Africa Continent (African Herbal Pharmacopoeia - AfrHP and African Pharmacopoeia), and the WHO structure.Fifty-six countries reported to the WHO have a national pharmacopoeia. Pharmacopoeia of the Eurasian Economic Union (EAEU), European Pharmacopoeia, African Pharmacopoeia, African Herbal Pharmacopoeia are indicated as pharmacopoeia used regional and subregional. As an international pharmacopoeia, there is

The International Pharmacopoeia within the WHO [3]. A national pharmacopoeia are developed and published by the national pharmacopoeia authority of their country.Information on the name, publisher country and language of the pharmacopoeia of which informations are included in the WHO-index and available from various sources, are briefly presented below in the Table 1 [3-8].

Table 1. Extensity, name, language and publisher country some of world pharmacopoeias[3-8].

Extensity	**Country- Name of Pharmacopoiea - Language**
National	Argentina – FarmacopeaArgentina – Spanish Austria – Austrian Pharmacopoeia – Russian Belarus – State Pharmacopoeia of the Republic of Belarus – Russian Brazil – Brazilian Pharmacopoeia – Portuguese/English/Spanish Brazil – Brazilian Homeopathic Pharmacopoeia – Portuguese/English/Spanish Brazil – National Formulary– Portuguese/English/Spanish Chile – FarmacopoeaChilena – Spanish China – Pharmacopoeia of the People's Republic of China – Chinese/English Croatia – Croatian Pharmacopoeia (HRF) – Croatian Czechia – PharmacopoeaBohemica – Czech Denmark – Pharmacopoea Nordica – Danish Egypt – Egyptian Pharmacopoeia – Arabic/English Estonia–PharmacaEstica – Estonian France – French Pharmacopoeia – French/English Germany – German Pharmacopoeia (DAB) –German Germany – German Homeopathic Pharmacopoeia (HAB) – German Greece – Greek Pharmacopoeia – Greek Hungary – PharmacopoeaHungarica – Hungarian India – Indian Pharmacopoeia – English Indonesia – Farmakope Indonesia – Indonesian Iran – Iranian Pharmacopoeia – Iranian Italy – Official Pharmacopoeia of the Italian Republic – Italian Japan – The Japanese Pharmacopoeia (JP) – Japanese/English Kazakhstan – The State Pharmacopoeia of the Republic of Kazakhstan (SPRK) – Kazakh/Russian Korea – The Korean Pharmacopoeia – Korean Lithuania – Lithuanian Pharmacopoeia – Lithuanian

	Mexico – Pharmacopoeia of the United Mexican States –Spanish Mexico – Mexican Herbal Pharmacopoeia– Spanish Mexico – Mexican Homeopathic Pharmacopoeia – Spanish Mexico – Pharmacopoeia of the United Mexican States – Spanish Pakistan – Pakistan Pharmacopoeia – English Philippines – Philippine Pharmacopeia – English Poland – FarmakopeaPolska – Polish Portugal – Farmacopeia Portuguesa – Portuguese Romanian – PharmacopeaRomână – Romania Russian Federation – State Pharmacopoeia of the Russian Federation – Russian Serbia - Serbian Pharmacopoeia - Serbian Slovakia – Codex Pharmaceutical Slovacus – Slovak Slovenia– FormulariumSlovenicum – Slovene Spain – Royal Spanish Pharmacopoeia – Spanish Switzerland – Pharmacopoea Helvetica – French/German/Italian Thailand – Thai Pharmacopoeia – English Thailand – Thai Herbal Pharmacopoeia – English Turkey – Turkish Pharmacopoiea (TP) – Turkish Ukraine – The State Pharmacopoeia of Ukraine – Ukrainian United Kingdom of Great Britain and Northern Ireland – British Pharmacopoeia – English United States of America – The United States Pharmacopeia and National Formulary (USP-NF) – English/Spanish Vietnam – Pharmacopoeia Vietnamica – Vietnamese/English
Regional &Subregional	Eurasia – Pharmacopoeia of the Eurasian Economic Union - Russian (official) European Pharmacopiea Members – European Pharmacopoeia – English/French Africa – African Pharmacopoeia – English Africa – African Herbal Pharmacopoeia (AfrHP) – English
International	WHO Geneva, Switzerland – The International Pharmacopoeia – English

There are written sources containing substances and preparations in the pharmaceutical field since ancient civilizations in various geographies around the world.The recently published pharmacopoeias compatible with today's pharmacopoeia understanding are respectively; the Russian Pharmacopoeia has been revealed in 1778, the Polish Pharmacopoeia in 1817, the United States Pharmacopeia in 1820, British Pharmacopoeia in 1864, Hungarian

Pharmacopoeia in 1871, German Pharmacopoeia in 1872, the Japanese Pharmacopoeia in 1886, Argentina Pharmacopoeia in 1893, the International Pharmacopoeia (WHO) in 1950, Chinese Pharmacopoeia in 1953, the Korean Pharmacopoeia in 1958, Indian Pharmacopoeia in 1960 and the European Pharmacopoeia in 1969. Many pharmacopieas have been developed, revised and enlarged until today [9-16]. As indicated in Table 1, most of them are available and national, four of them are regional/subrerional and one of them is international. The pharmacopoeias about which information is available are briefly indicated below.

National Pharmacopoeias

The United States Pharmacopoiea– National Formulary – USP-NF

The first national pharmacopoeia in America was published in 1820 with the idea of creating a national pharmacopoeia for authorized drugs and preparations [17].USP-NF is published by the United States Pharmacopeia [18].USP-NF contains official substance (ingredient) and product monographs for official articles recognized in USP-NP. USP-NF also includes the monographs for compounded preparations.With some exceptions, such as the articles contained in the Global Health monographs, all articles that have monographs in the USP-NF are legally marketed or included in the articles marketed in the US. A USP-NF monograph for an official substance, product, or preparation may consist of various components, including the requirements; and a specification. General chapters provide frequently cited procedures, sometimes with acceptance criteria, in order to compile into one location repetitive information that is applicable to many monographs. USP-NF also includes *Dietary supplements* monographs, *NF Admissions/Annotations*, *Excipients*, *NF* monographs, *General Test and Assays*, *Reagents*, *Reference tablets* monographs [19].

The British Pharmacopoeia – BP

The British Pharmacopoeia has been providing official standards for medicines since 1864 [20].The Pharmacopoeial standards are designed to complement and assist the licensing and inspection processes and are part of the overall system for safeguarding purchasers and users of medicinal products in the UK. The British Pharmacopoeia is published by the British Pharmacopoeia Commission, Medicines and Healthcare products Regulatory Agency-MHRA.The British Pharmacopoeia contains publicly available, legally enforceable standards that provide an authoritative statement of the quality that a product, material or article is expected to meet at any time during its period of use. It includes General Notices, Monographs (Medicinal and Pharmaceutical Substances, Formulated Preparations: General Monographs, Formulated Preparations: Specific Monographs, Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products, Materials for use in the Manufacture of Homoeopathic Preparations, Blood-related Products, Immunological Products, Radiopharmaceutical Preparations, Surgical Materials), Infrared Reference Spectra chapter and Veterinary Volume [21].

The Japanese Pharmacopoeia – JP

Japanese Pharmacopoeia was first published in 1886 [22].The Japanese Pharmacopoeia is promulgated by the Ministry of Health, Labour and Welfare-MHLW that is an official document that defines the specifications, criteria and standard test methods necessary to properly assure the quality of medicines in Japan.The Japanese Pharmacopoeia includes General Notices, General Rules for Crude Drugs and Preparations, General Tests, Processes and Apparatus (Chemical Methods, Physical Methods, Powder Property Determinations, Biological Tests/Biochemical Tests/Microbial Tests, Tests for Crude Drugs, Tests for Preparations, Tests for Containers and Packing Materials, Reference Standards; Standard

Solutions; Reagents, Test Solutions; Measuring Instruments, Appliances, etc.), Official Monographs, Crude Drugs and Related Drugs, Infrared Reference Spectra, Ultraviolet-visible Reference Spectra and General Information (Physics and Chemistry, Solid-state Properties, Biotechnological/Biological Products, Microorganisms, Crude Drugs, Drug Formulation, Containers and Package, Water, Reference Standards, International Harmonization) monographs [23].

The Turkish Pharmacopoiea- TP

The first known Turkish national standard about materials, substances and preparations in the world was declared in 1502 during the time of Ottoman Empire of Sultan Beyazıt Han. The process that started with the publication of the first pharmacopoeia in Istanbul in 1818 has developed and diversified until today. The original text of the "Kanunname-iİhtisab-ı Bursa" in Istanbul Topkapı Museum Revan Library was prepared by Sultan II. Bayezid Han in 1502 as edict. In this document, the quantity, weight, size and packaging characteristics and standards of various materials such as herbal products, textiles, food products and salt have been determined. The standard has been reprinted by the Turkish Standards Institution with the preservation of its original text and dimensions [9-12]. The first official pharmacopoeia of the Republic of Turkey which contains 659 monograph was published in 1930 under the name of “Turkish Codex”[13]. The Republic of Turkey is one of the 39 member states of the European Pharmacopoeia. European Pharmacopoeia used officially in Turkey but also the Turkish Pharmacopoeia continues its existence. The Turkish Pharmacopoeia is prepared by the Turkish Medicines and Medical Devices Agency-TMMDA and the official broadcast is “Turkish Pharmacopoeia Journal”. National monographs that are newly added, updated, corrected in the Turkish Pharmacopoeia are announced before this publication. Turkish Pharmacopoeia includes European Pharmacopoeia monographs as well as national monographs. It also has a section containing magistral preparation monographs in a separate volume. After elaborating monographs such as chemical, herbal, biological or biotechnological products and finished products, they are published in the Turkish Pharmacopoeia Journal and then in the Turkish Pharmacopoeia and become official.Since the 7thversion of the Turkish Pharmacopoeia published in 2017, the pharmacopoeia is being expanded with the increasing number of national monographs every year. In the 2019 version, the number of national monographs has reached thirty two and most of them are monographs of medicinal and aromatic herbal ingredients [24].

Pharmacopoeia of the People's Republic of China - ChP

The ministry of health published theRebublic of China’s first pharmacopoeia as Chinese Pharmacopoeia in 1953. Under the umbrella of the China Food and Drug Administration-CFDA, the Chinese Pharmacopoeia Commission-ChPC and its stakeholders (drug control institutions, research institutions, universities and drug manufacturers) prepare the Chinese Pharmacopoeia in line with the basic principles, goals and requirements of the era. The Chinese Pharmacopoeia contains monographs of medicinal materials and the prepared slices of Chinese crude drugs, vegetable, oil fat and extracts, single-item preparations, chemical drugs, antibiotics, biochemical drugs and radioactive drugs, pharmaceutical excipients andbiologicals. General Chapters includes general requirements of preparations, testing methods, standard substances, reagents and guidelines [25,26].

Farmacopea Argentina

Farmacopea Argentina is published by The National Administration of Medicines Food and Medical Technology-ANMAT. The 8th Edition (Vol 1,2,3,4) was released in 2011 and its language is Spanish [3,27].

Brazilian Pharmacopoeia

Brazilian Pharmacopoeia is published by Pharmacopoeia Coordination Brazilian Health Surveillance Agency-ANVISA in three languages, Portuguese, English and Spanish. Apart from Brazilian Pharmacopoeia, Brazilian Homeopathic Pharmacopoeia (Portuguese/English/Spanish), National Formulary (Portuguese/English/Spanish), Herbal Medicines National Formulary (Portuguese/Spanish), Homeopathic Medicines National Formulary (Portuguese/English/Spanish), Herbal Medicines Memento (Portuguese) are also used in Brasil[3,28].

German Pharmacopoeia - DAB

German Pharmacopoeiais published by Federal Institute for Drugs and Medical Devices-BfArM in German. Also German Homeopathic Pharmacopoeia-HAB is used in Germany [3,29].

Indian Pharmacopoeia

Indian Pharmacopoeia Farmacopea is published by Indian Pharmacopoeia Commission-IPC on behalf of the Ministry of Health and Family Welfare in English. Indian Pharmacopoeia contains procedures for analysis and specifications for the determination of quality of pharmaceutical substances, excipients and dosage forms. IP monograph for an official substance or preparation includes the article's definition, description, identification, packaging, storage, specifications, impurities, assay and specific tests, one or more analytical procedures for each test, acceptance criteria, other requirements etc. It includes General Chapters and Reference Data, General Notices, Dosage Forms (General Monographs), Drug Substances, Dosage Forms and Pharmaceutical Aids, Vaccines and Immunosera for Human Use, Herbs and Herbal Products, Blood and Blood-related Products, Biotechnology Products; Veterinary Products [30,31].

Iranian Pharmacopoeia

Persian pharmacy history dates back to ancient times. *Qarabadins* were a kind of pharmaceutical books which was the first generation of pharmacopeias in the history, and these books were a registry of drugs and preparations containing dosage forms, preparation procedures, considerations, dose of administrations, shelf life, etc. The transition to modern pharmacopoeia in Iran started to be written recently, and modern medicine has replaced the Persian medicine, and new pharmacy education and practices have started. The first Iranian pharmacopoeia was published in 2004 by Iranian Ministry of Health. During lateryears, five other volumes of this pharmacopeia were published. The last (6^{th}) volume was published in 2015 [32,33].

Pharmacopoeia of the United Mexican States

Pharmacopoeia of the United Mexican States is published by Permanent Commission of the Pharmacopoeia of the United Mexican States in Spanish. Also Mexican HerbalPharmacopoeia, Mexican Homeopathic Pharmacopoeia, Medical devices Supplement and Pharmacies Supplement is used in Mexico [3,34].

Thai Pharmacopoeia

Thai Pharmacopoeia is published by Thai Pharmacopoeia Committee Bureau of Drug and Narcotic Department of Medical Sciences on behalf of the Ministry of Public Health in English [3].It includes Raw material monographs, finished product monographs and infrared reference spectras [35]. Also Thai Homeopathic Pharmacopoeia is used in Thailand [3].Homeopathy treatment is a branch of alternative medicine that is the second most widely used system of medicine in the world and is the fastest growing. Today, homeopathy is preferred as a potential treatment by many people. In Thailand, although this treatment is quite new, homeopathy is on a rapid rise and it is becoming a booming medical business [36].

Regional and Subregional Pharmacopoeias

The European Pharmacopoeia - EP

The 1st Edition of European Pharmacopoeia was published as three bound volumes between 1968 and 1976 [37].By replacing the Convention on the Elaboration of the European Pharmacopoeia with the Convention Protocol signed by the Governments of 38 member states (Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Republic of Moldova, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom) and the European Union, the European Pharmacopoeia was prepared under the umbrella of the Council of Europe. The preparation of the Pharmacopoeia is the responsibility of the European Pharmacopoeia Commission (‘the Commission'), appointed in accordance with Article 5 of the above-mentioned Convention. It is composed of delegations appointed by the Contracting Parties. Each delegation consists of not more than three members chosen for their competence in matters within the functions of the Commission [38].The European Pharmacopoeia is within the body of European Directorate for the Quality of Medicines & HealthCare-EDQM and the official broadcast is Pharmeuropa. Monographs that are newly added, updated, corrected or planned to be deleted in the European Pharmacopoeia are announced before this publication. European Pharmacopoeia includes, General chapters (General notices, Methods of analysis, Materials for containers and containers, Reagents, General texts), General monographs, Monographs on dosage forms, Vaccines for human use and veterinary use, Immunosera for human use and veterinary use, Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations, Sutures for human use and veterinary use, Herbal drugs and herbal drug preparations, Homoeopathic preparations and monographs [3,39,40].

Pharmacopoeia of the Eurasian Economic Union

1st Edition of Pharmacopoeia of the Eurasian Economic Union is published by Pharmacopoeial Committee of the Eurasian Economic Union on behalf of the Eurasian Economic Commission in 2019. It is planned to publish the official language in Russian every 3 years. Participating countries in the Pharmacopoeia the Eurasian Economic Union: Armenia, Belarus, Kazakhstan, Kyrgyzstan and the Russian Federation [3,41].

African Pharmacopoeia

African Pharmacopoeia is published by African Union Scientific Technical Research Commission-STRC in English. African Herbal Pharmacopoeia -AfrHP, another official source used in Africa is published by Association for African Medicinal Plants Standards in English [3,42].

International Pharmacopoeia

The International Pharmacopoeia-Ph.Int.

The International Pharmacopoeia was born in 1874 based on the need to standardize terminology, determine the composition and dosage of drugs.Ph.Int. includes the accumulation of recommended procedures for analysis and specifications for the identification of pharmaceutical substances, adjuvants and dosage forms intended to serve as resource materials for reference or adaptation by any WHO Member State intended to build pharmaceutical needs [43,44].Ph.Int. compared to national and regional pharmacopoeias, it is published by WHO as a recommendation to help achieve a global quality specificity by providing international standards (including less technically claiming alternatives where needed) for pharmaceutical products, adjuvants and dosage forms to be accepted by Member States [2]. It includes General Notices, Appendices to the General Notices, Pharmaceutical Substances monographs, Dosage Forms (General and specific monographs), Radiopharmaceuticals (General monographs, Specific monographs, Methods of analysis (Physical and physicochemical/Chemical/Biological methods), Supplementary information), Methods of Analysis (Physical and physicochemical methods, Chemical methods, Biological methods, Methods for materials of plant origin and Pharmaceutical technical procedures), Infrared Reference Spectra chapter, Reagents, test solutions and volumetric solutions and Supplementary information [43].

Content of Pharmacopoeias

Pharmacopoeias consist of general chapters and medicinal and pharmaceutical substances monographs,starting with the preface, introduction and general notices. The monographs whose tıtle/monograph number has changed and new, revised, corrected, deleted monograph information is indicated. Methods of analysis chapter describing many analytical methods to be applied in analysis with biological tests and assays, Materials for containers and containers chapter describing the materials are used for the manufacture of containers for pharmaceutical use, Reagents chapters containing a description of the solutions prepared for tests and analyzes with specified standards, Monographs on Dosage forms, Vaccines, Immunoseras, Blood-related Products Immunological Products, Radiopharmaceuticals, medical devices Herbal drugs and herbal drug preparations, Homoeopathic preparations and monographs, Infrared/Ultraviolet-visible Reference Spectra information of chemicals, Formulated Preparations and finished product monographs can be described as parts of pharmacopoeia [19,21,23,39].

The quality control of pharmaceutical products has a great prospect in terms of the safe access to treatment that patients need. The quality of the pharmaceutical products used must comply with relevant internationally accepted criteria. Quality in pharmaceutical products is a broad concept covering all aspects that affect the efficacy and safety of these products. All of the measures that require the assurance of pharmaceutical quality constitute the quality assurance system. The Quality Assurance system consists of Quality Management (QM), Quality Assurance (QA) and Good Manufacturing Practices (GMP) and Quality Control (QC). Pharmaceutical products are subjected to quality control criteria and analysis within the scope of internationally accepted standards and guidelines specified or guided, including formulation, place and form of use. Pharmacopoeias shed light on many aspects of quality control analyzes in pharmaceutical products [45].Basically, pharmaceutical scientists should be careful to select the material in accordance with the appropriate standards and specified quality criteria, with very careful handling of the material's use process to obtain a consistent pharmaceutical product [46].

Monograph Elaboration Tecniques

Monographs are elaborated or revised according to certain accepted patterns. EDQM and WHO have published detailed documents on monograph elaboration techniques and procedures. The published documents are updated by intermediate and published on the official web pages [47]. Countries involved in monograph studies follow and implement these procedures.EDQM has developed detailed guides for monograph elaboration as well as study techniques and publishes new ones as needed. Brief information about these guides is given below.

Style Guide of the European Pharmacopoeia has been produced to help all those involved in the preparation of monographs for the European Pharmacopoeia-Ph.Eur.: the groups of experts, secretaries of these groups, translators, national secretariats. The aim of the *Style Guide* is to provide the means of drafting clear unambiguous texts, with similar requirements presented in the same way in every monograph. A uniform style is of great help in conveying information in an easily understandable and unambiguous manner. An analyst who has already carried out a test prescribed in the Ph. Eur. will find it easier to set up and carry out a similar test presented in the same way [48].

*A guide to the graphic representation and nomenclature of chemical formulae in the European Pharmacopoeia*is the guide on nomenclature and graphic representation of chemical formulae has been prepared to reply to a number of questions from the European Pharmacopoeia Commission and users of the Ph. Eur. [49].

Technical guide for the elaboration of monographs is a guide for the authors of monographs and also a means of communicating the principles for the elaboration of monographs to the users of the European Pharmacopoeia, especially industry, licensing authorities and official medicines control laboratories [50].

Guide for the elaboration of monographs on vaccines and immunosera for human use is intended to provide guidance to authors, contributors and users of European Pharmacopoeia on the elaboration of monographs for vaccines and other immunological human medicinal products [51].

Technical Guide for the elaboration of monographs on synthetic peptides and recombinant DNA proteins is intended to provide guidance to authors, contributors and users of the European Pharmacopoeia on the elaboration of active substance monographs for synthetic peptides and products of recombinant DNA technology, referred to as rDNA proteins throughout the document [52].

*General principles for monographs on finished products containing chemically defined active substances*is intended to provide additional information to users on how to read and apply future individual FP monographs. It shall be read in conjunction with the European Pharmacopoeia. General Notices, the relevant dosage form monograph and the general monograph on *Pharmaceutical Preparations* [53].

Guide for the elaboration of monographs on homoeopathic preparations is about stocks for homoeopathic preparations may be of a mineral, chemical, botanical, zoological or human

origin. This Guide develops the specific points which are appropriate to monographs for homoeopathic preparations, and which are not presented in the Technical Guide for the Elaboration of Monographs (referred to as the Technical Guide) and of the Ph. Eur. Style Guide [54].

*Technical Guide for the elaboration and use of monographs on human plasma-derived products*is intended to provide guidance to authors, contributors and users of European Pharmacopoeia monographs and general chapters on medicinal products derived from human blood and human plasma [55].

*Guide for the elaboration of monographs on radiopharmaceutical preparations*is usedfor the elaboration of monographs on radiopharmaceutical preparations supplements the latest versions of both the Style guide of the European Pharmacopoeia and the Technical Guide for the elaboration of monographs. In this guide, attention is given only to those subjects that are particular to radiopharmaceutical preparations [56].

Technical Guide for the elaboration and use of monographs for vaccines and immunological veterinary medicinal products is intended to provide guidance to authors, contributors and users of European Pharmacopoeia monographs on veterinary vaccines and other immunological veterinary medicinal products[57].

Technical Guide for the elaboration of monographs on fatty oils and derivatives, a guide which is using to achieve harmonised monographs. Accordingly, in revision of a monograph or in the creation of a new monograph, it should be added to the monograph if it is useful and suitable, taking into account the analytical parameters specified in these guidelines [58].

*Technical Guide for the elaboration of monographs on herbal drugs and herbal drug preparations*is a guide for developing specific points unavailable in the above-mentioned general Guidelines regarding to herbal drug and herbal drug preparations monographs. It is recalled that all tests and assay methods described in a monograph must be validated according to the procedures stated in the Technical guide [59].

*Procedure for the elaboration, revision and omission of monographs and other texts for The International Pharmacopoeia*was created for Ph.Int. monographs. Its main purpose is to ensure the quality of the drug for safe and effective use. Monographs are developed in accordance with the principles in the Good Pharmacopoeia Practices (GPhP), in a clear process and aim to harmonization and convergence of compendial quality standards to ultimately increase access to affordable, quality-assured medicines [60].

CONCLUSION

In parallel with the advances in the scientific and technological fields and the developments in the pharmaceutical and analytical fields, the development and revisions of the pharmacopoeias will continue.

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