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Development and Approval of Quality Standards for Pharmaceutical Substances of Plant Origin in the Russian Federation

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Abstract

Issues related to the creation of modern normative documentation specifying the quality of pharmaceutical substances of plant origin (medicinal plant material) are considered in this article. A brief historical background of the State Pharmacopoeia development is presented. With the help of a system research method and information-analytical method, a chart for the approval and inclusion of general pharmacopoeial monographs projects and pharmacopoeial monographs projects on medicinal plant materials in the State Pharmacopoeia of Russian Federation was developed and proposed taking into account Russian legislation.

Keywords: State pharmacopoeia of Russian Federation, general pharmacopoeial monographs, pharmacopoeial monographs, pharmaceutical substances of plant origin, quality of herbal drugs, medicinal plant material

INTRODUCTION

Medicinal plants (MP) and medicinal plant materials (MPM) are sources for the production of pharmaceutical substances of plant origin (PSPO), preparations produced on its basis are widely used in medical practice.

According to Federal Law of the Russian Federation No. 61-FZ dated 12.04.2010, "On drugs circulation" (as amended and supplemented, effective date 01.01.2017), the drug quality is determined by its compliance with the requirements of the pharmacopoeial monograph (PM), or, in the case its absence, with the requirements of the normative documentation or normative document [1]. In this regard, so much attention is paid to the development and updating of the State Pharmacopoeia of the Russian Federation (SPRF).

In January 2016 the SPRF 13th edition (SPRF, 13th ed.) came into force [2]. The history of the SP of Russia dates back 250 years: in 1765 the Military Pharmacopoeia of Russia was published, then in 1778 - the Russian Pharmacopoeia was published in Latin. The Soviet period ended with the publication of Pharmacopoeia 11th edition. A new stage began in the 21st century: the first part of the SPRF 12th edition was published in 2007. It was decided not to republish the following parts, but, after reviewing and reworking the monographs, include them in the SPRF 13th edition [3-5].

The main goal of the SPRF is to standardize the quality of drugs that are brought to the Russian pharmaceutical market.

METHODS

Based on the system research method, information-analytical method, a chart was developed and proposed for the approval of general pharmacopoeial monographs (GPM) projects and PM projects on medicinal plant materials and inclusion in SPRF. The study used the legislative acts of the Russian Federation, normative documentation.

RESULTS AND DISCUSSION

Center for Pharmacopoeia and International Cooperation (CPIC) of the FSBI "Scientific Center for Expert Examination of Medicinal Products" (FSBI SCEEMP) of the Ministry of Health of Russian Federation (MHRF) is the main organization engaged in the development, as well as in the update of GPM and PM included in the SPRF. In addition to the direct development of the GPM and PM, the organization is engaged in conducting an examination of the methods and procedures presented in the PM projects, as well as the prescribed normative requirements. CPIC is engaged in preparation of methodical recommendations "Rules of drafting, writing and formalization of the normative documentation for pharmaceutical substances", which are included in the 4-volume "Guideline for expertise of drugs" of FSBI SCEEMP [6].

The CPIC performs its activities in close contact with the Council of the MHRF on the State Pharmacopoeia (CMHRFSP), as well as the Pharmacopoeia Committee of the Union, which are reviewing the GPM and PM for their scientific validity and the need for practical application.

CMHRFSP has the following functions:

- review of the GPM and PM projects, its supplements.
- making a decision for approving the proposed projects or their disapproval, specifying the reasons.
- consideration of the draft SP prepared for publication and (or) changes (additions) to the current publication and making a decision for their approval or for further development.
- review and discussion of the long-term plan for the SP development [7].

We have developed and proposed a chart reflecting the procedure for the creation and inclusion of GPM and PM on the MPM in the SP. This chart is shown at Figure 1 and is compiled taking into account Russian legislation and normative documentation for PSPO.

Drug circulation entities submit applications to The Department of State Regulation of Drug Circulation (DSRDC) of the MHRF, whose director headed the CMHRFSP. Then the applications are distributed between FSBI SCEEMP and CMHRFSP. PM projects together with accompanying documentation can be sent to FSBI SCEEMP by research organizations involved in the MPM standardization. After reviewing, the PMs are submitted to the MHRF for approval. After approval, the MHRF issues an order, and PMs are included in the SP [8].

At present the SPRF XIII edition includes 229 GPMs and 179 PMs, of which 2 GPMs and 55 PMs specify the MPM quality [2].

GPM and PM projects of the SPRF XIII edition were developed in accordance with modern standardization procedures and quality control of the MPM [9]. Normative documents projects (PM) of the SPRF XIII on the MPM comply with the requirements of the Guidelines for Good Pharmacopeia Practice (GPhP) [10] and contain the following main sections: name of the MP; definition of MPM; identity; testing; quantitation; storage; packing, marking and transportation.

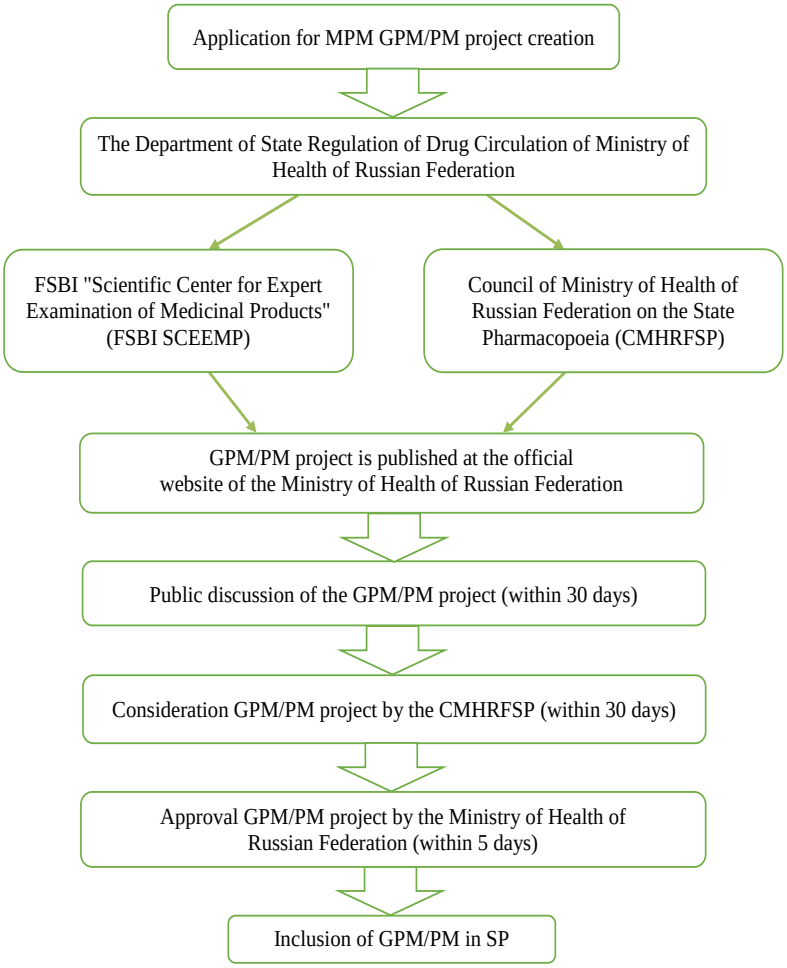

Figure 1. Stages pf the GPM/PM project on the MPM processing for inclusion in the SP

Conclusion

There are several aspects of creating Russian quality control standards for medicinal plant materials and herbal drugs intended primarily for inclusion in the State Pharmacopoeia of the Russian Federation. The main criterion is harmonization with the foreign pharmacopoeias requirements [11-15]. Harmonization of requirements will contribute to improving the quality of Russian drugs and help to enhance competitiveness in the global pharmaceutical market.

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