

Macao Funding Scheme for Key R&D Projects 2019 Application Guideline for Projects of Traditional Chinese Medicines Development and Quality Control

I. Background

As the key content of our country's "Thirteenth Five-Year Plan", the Chinese medicine industry is one of the few industries with independent intellectual property rights and great potential for independent innovation. It is also a strategic emerging industry making increasing contribution to health, economy, science and technology, culture and ecological resources. With its good research foundation in modernized Chinese medicine research, Macao's continuous investment since the Ministry of Science and Technology approved Macao to establish the State Key Laboratory of Quality Research in Chinese Medicines has constantly achieved results the field in terms of personnel training, scientific research development and international platform construction, continuously enhancing Macao's influence at home and abroad.

In order to give full play to Macao's advantages in traditional Chinese medicines development and quality control, further integrate existing resources, and improve research and development capabilities and industrialization level, the Macao Science and Technology Development Fund (FDCT) has sought the opinions of researchers in relevant fields in Macao and experts in Mainland China to come up with the city's key R&D plan for traditional Chinese medicines development

and quality control. The plan intends to meet the needs of China and play the role of Macao in phases by constantly improving local level of research and development and industrialization in the field of artificial intelligence. It will help promote the moderate diversification of Macao's economy with technology innovations that contribute to the development of traditional Chinese medicines and healthcare industry, as well as the construction of the international innovation and technology hub in the Guangdong-Hong Kong-Macao Greater Bay Area, and contributes to building China into an innovation-driven country.

II. Overall Objectives

The scheme aims at supporting projects that highlight the advantages and characteristics of traditional Chinese medicines, combine tradition and innovation, make full use of modern science and technology, strengthen the modern research of traditional Chinese medicine, accelerate the breakthrough of key technologies such as quality evaluation and control of traditional Chinese medicine, enhance the level of international scientific and technological cooperation in the field, and accelerate the development of Chinese medicine and health industry.

III. Research Directions

This guideline focuses on the three directions, namely quality assessment and quality control of commonly used traditional Chinese medicines and

natural medicines, research and development of new Chinese medicines, and research on international standards of traditional Chinese medicines and natural medicines, conducting integrated design for the whole chain from quality control to new drug development to standard research.

The implementation period for each direction is 3 years at maximum, and the total amount of grants funded by the FDCT for these three directions is MOP 30 million.

1. Research on quality assessment and quality control of commonly used traditional Chinese medicines and natural medicines

Content of Research: Research on multi-source Chinese herbal medicines and decoction pieces identification and rapid suitability test technology for Chinese medicines; Research on pharmacodynamic substance basis and quality control methods for Chinese herbal medicines and decoction pieces (including imported natural medicines); developing more than 5 kinds of variety identification and rapid suitability test technologies, and 3 kinds of pharmacodynamic substance basis and quality control methods for Chinese medicines.

Description: The leading entity should have a solid work foundation; enterprises with relevant research foundations are encouraged to participate in the projects.

2. Research and development of new Chinese medicines

Content of Research: Conducting research on R&D technology

and product development of traditional innovative Chinese medicines targeting critical diseases and health needs; establishing innovative drug development technologies for cardiovascular and cerebrovascular diseases, neurodegenerative diseases or cancer, and completing one case of new drug research data that meets the requirements for pre-clinical approval.

3. Research on international standards of traditional Chinese medicines and natural medicines

Content of Research: Developing research methods for quality standards of traditional Chinese medicines and natural medicines and internationally recognized quality standards; studying international standards for detection methods and limits of harmful residues of traditional Chinese medicines and natural medicines; adding 3 or more traditional Chinese medicines or natural medicines that satisfy international standards such as the United States Pharmacopoeia, the European Pharmacopoeia or ISO; proposing detection methods and setting limitation of harmful residues in traditional Chinese medicines and natural medicines.

Description: Varieties that have been adopted by the international mainstream pharmacopoeias and ISO should not be re-applied for this scheme.

IV. Application Requirements

The applicant entities should submit the application in the form of projects according to the content of research in one of the directions listed in this guideline. Any project with subject(s) under it should be declared as a whole that covers all the evaluation criteria. Unless otherwise stated, there should be no more than three subjects under each project. The leading entity of the project must be a Macao institution. Entities outside Macao are encouraged to participate in the form of cooperation. Each project should contain no more than 6 entities.

The maximum amount that can be applied for by each project is MOP 15 million.

V. Experts Involved in Guideline Preparation

Zhu Xiaoxin	Researcher, Institute of Chinese Materia Medica, China Academy of Chinese Medical Sciences
Yu Boyang	Professor, China Pharmaceutical University
He Yi	Researcher, National Institutes for Food and Drug Control
Jia Tianzhu	Professor, Liaoning University of Traditional Chinese Medicine