

Macao Funding Scheme for Key R&D Projects 2020

Application Guideline for Projects of Classical TCM

Prescription Preparations and Standard R&D and Industrialization

I. Background

The *Opinions of the CPC Central Committee and the State Council on Promoting the Preservation, Innovation and Development of Traditional Chinese Medicine (TCM)*, released in 2019, states the country's goals of promoting TCM preservation, innovation and development as well as enabling the TCM sector in the Guangdong-Hong Kong-Macao Greater Bay Area to stand on the high ground of the industry. In other words, it sets the development of the TCM industry as a national strategy while defining the positioning of the sector in the Greater Bay Area.

Preparation is a major form of clinical medication prescribed by TCM doctors. Classical prescription preparations from ancient China were recorded in the classics of ancient Chinese medicine and known for their distinctive features and merits. They remain widely used today for its good efficacy in medical treatment. These preparations have attracted great attention, since the release of the *Catalogue of Ancient Classical Prescription Preparations (first batch)* by the National Administration of Traditional Chinese Medicine in 2018, with people giving increasing weight to their future development. The country also published policy documents to support the development of medications based on these classical TCM prescriptions and R&D

in their preparations. They include *Outline of the Strategic Planning for the Development of Traditional Chinese Medicine (2016-2030)* and *Regulations for Streamlining Registration and Review Processes and Management of Compound Preparations for Ancient Classical TCM Prescriptions*.

The Macao SAR government attaches high importance to R&D in and industrialization of classical prescription preparations. The Policy Address 2020 states the goal of “developing classical TCM prescription pharmaceuticals and building a characteristic TCM innovation, R&D and commercial application platform with its own patent products by using Macao’s unique resources such as the State Key Laboratory of Quality Research in Chinese Medicine (SKL-QRCM)”. The SKL-QRCM, established with the approval of the Ministry of Science and Technology in 2010, has made substantial achievements after years of active efforts in training of TCM professionals, R&D, platform building and other aspects for the development of Macao’s TCM brand.

The Science and Technology Development Fund (FDCT) of Macao proposes this key R & D project, developed with the expertise of mainland experts and taking into the opinions of Macao’s researchers in relevant areas, as a way to promote a full use of Macao’s R&D prowess in TCM as well as the modernization of TCM services and industrialization of TCM. FDCT expects that the project will help Macao bring its strengths into full play in an organized way to meet the country’s needs, fostering Macao’s due economic diversification through technological innovation. It is hoped that the classical TCM prescription preparation research will trigger the

growth of the TCM comprehensive health industry, in support of the development of the International Innovation and Technology Hub in the Greater Bay area, thereby contributing to China's development into an innovative country.

II. Overall Objectives

To encourage research on primary standards and preparations revolving around classical TCM prescriptions, which promotes TCM's advantages and the integration of TCM innovation and preservation, for shaping a development model for classical TCM prescription preparations and nurturing a capacity for their commercial application at the service of the Greater Bay Area; further facilitate the internationalization of Macao's TCM industry so it can provide technical support to the SAR government's TCM monitoring system.

III. Research Fields

The Guideline targets the field of Classical TCM Prescription Preparations and Standard R&D and Industrialization. Projects in the field should be executed in no more than 3 years.

Researchers should, in carrying out their work, take reference from the *Regulations for Streamlining Registration and Review Processes and Management of Compound Preparations for Ancient Classical TCM Prescriptions* and other traditional botanical drug registration guidelines from other countries. The work includes selecting and verifying ancient classical TCM prescriptions, and research on the origins of related medicinal herbs, their processing

methods, preparation techniques, quality transfer and the safety of their use in non-clinical scenarios for developing primary standards, quality standards and preparations concerned. The ultimate goals are forming a classical prescription preparation development technique, a relevant TCM research system covering quality standards and preparations creation and an innovative industry-university-research platform. Other goals are gaining two patents concerning the development of classical prescription preparation, completing two studies on these preparations in addition to submitting applications to the drug regulatory authority together with drug manufacturers and getting an approval for them.

IV.Application Requirements

Every applying entity should file the application for its work in the form of a project that covers research topics in any of the fields stated in this Guideline. The entity should apply for each of its projects as a whole and the projects should in principle cover all the required performance indicators. Unless otherwise specified, a project should include no more than three topics. The entity leading the project should be a local one but we encourage cooperation with entities from outside Macao. Every project should be undertaken by no more than 6 entities, and the people in charge of the project and the research should be eligible for full-time work in Macao.

The maximum application amount for each project is MOP150 million.

V. Experts Involved in Drawing up the Guideline

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