

Macao Funding Scheme for Key R&D Projects 2024

Application Guideline for Projects of Classical TCM Prescription Preparations and Standard R&D and Industrialization

I. Background

Preparation is a major form of clinical medication prescribed by doctors of traditional Chinese medicine (TCM). Classical prescription preparations from ancient China recorded in the classics of ancient Chinese medicine are known for their distinctive features and merits. They remain widely used today for the good efficacy in medical treatment. The future development of these preparations has attracted great attention from the entire industrial chain of TCM, since the release of the *Catalogue of Ancient Classical Prescription Preparations (first batch)* by the National Administration of Traditional Chinese Medicine in 2018. The country also published policy documents to support the development of new medications based on these classical TCM prescriptions and R&D in their preparations. These documents include *Outline of the Strategic Planning for the Development of Traditional Chinese Medicine (2016-2030)*, the *Opinions on Promoting the Preservation, Innovation and Development of Traditional Chinese Medicine*, and the *Several Policies and Measures for Accelerating the Development of Traditional Chinese Medicine Characteristics*. In 2022, the General Office of the State Council issued the “14th Five-Year Plan” for the *Development of Traditional Chinese Medicine* (hereinafter referred to as the “Plan”) to comprehensively deploy the TCM-

related tasks during the “14th Five-Year Plan” period. The Plan clearly proposes to “strengthen the R&D of new TCM drugs based on ancient classical TCM prescriptions, empirical prescriptions from renowned old TCM doctors, active ingredients or components”.

The Macao SAR Government prioritizes the R&D and industrialization of classical prescription preparations. The *Second Five-Year Plan for Economic and Social Development of the Macao Special Administrative Region (2021-2025)* proposes to “further allocate resources to promote the R&D of classical TCM prescriptions, innovative R&D of TCM, quality control and standardization technology of TCM, and development of TCM health products”. The *Policy Address for the Fiscal Year 2024* proposes to “facilitate the high-quality development of the TCM and big health industry”, “build an influential platform for the development of technology systems and innovations for classical TCM prescription preparations in Macao to stimulate the industrialization of TCM and attract more big health and pharmaceutical enterprises to set up their operations in Macao”.

In order to fully exert Macao’s R&D prowess in TCM, promote the modernization of TCM services and industrialization of TCM, the Science and Technology Development Fund (FDCT) has proposed this Scheme for Key R&D Projects after taking into opinions from Macao’s researchers in relevant fields and seeking expertise from mainland experts. It aims to help Macao bring its strengths into full play in a planned and step-by-step manner to accommodate the needs of the country, thus boosting Macao’s appropriate economic diversification through technological innovation. It is expected that the classical TCM prescription preparation research will trigger the growth of the TCM and big

health industry, in support of the development of the international innovation and technology hub in the Guangdong-Hong Kong-Macao Greater Bay Area, thereby contributing to China's development into an innovative country.

II. Overall Objectives

It aims 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 that it can provide technical support to the SAR Government's TCM monitoring system.

III. Research Field

Research Field: 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.

Performance indicators:

- (1) Obtaining 2 or more patents concerning the development of classical TCM prescription preparation.
- (2) Completing 2 studies on classical TCM prescription preparations.
- (3) Submitting applications to the drug regulatory authority and getting approval for them.
- (4) The Technology Readiness Level (TRL) of classical TCM prescription preparations shall achieve TRL 8.

IV. Application Requirements

- (1) The lead applicant shall be a Macao entity, and the project shall be led or participated by enterprises, which shall provide supporting funds of no less than 50% of the FDCT fund. If an enterprise participates in the project, it shall be a Macao or Hengqin enterprise.
- (2) A formal cooperation agreement shall be provided if the project is collaborative.
- (3) The project duration is 4 years. The maximum application amount for each project is MOP 15 million.