

The Regulations on the Administration of Record-Filing for Pharmacy Technicians from the Macao Special Administrative Region Practicing in Drug Retail Units in the Guangdong-Macao In-Depth Cooperation Zone in Hengqin are promulgated

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The Regulations on the Administration of Record-Filing for Pharmacy Technicians from the Macao Special Administrative Region Practicing in Drug Retail Units in the Guangdong-Macao In-Depth Cooperation Zone in Hengqin, adopted at the 14th Session of the Standing Committee of the 10th People's Congress of Zhuhai Municipality on May 26, 2023, are hereby promulgated and shall come into force on August 1, 2023.

Standing Committee of the Zhuhai Municipal People's Congress May 26, 2023

Regulations on the Administration of Record-Filing for Pharmacy Technicians from the Macao Special Administrative Region Practicing in Drug Retail Units in the Guangdong-Macao In-Depth Cooperation Zone in Hengqin
(Adopted at the 14th Session of the Standing Committee of the 10th People's Congress of Zhuhai Municipality on May 26, 2023)

Article 1 In order to advance the building of the Guangdong-Macao In-Depth Cooperation Zone in Hengqin (hereinafter referred to as the Cooperation Zone) and facilitate the convenient and orderly provision of services by pharmacy technicians from the Macao Special Administrative Region (hereinafter referred to as Macao) in the Cooperation Zone, these Regulations have been formulated in accordance with the basic principles of relevant laws and administrative regulations, as well as the provisions of the Outline of the Plan for the Development of the Guangdong-Hong Kong-Macao Greater Bay Area, the Master Plan of the Development of the Guangdong-Macao In-Depth Cooperation Zone in Hengqin and the Regulations on the Promotion of the Development of the Guangdong-Macao In-Depth Cooperation Zone in Hengqin, and in light of the actual situation of the Cooperation Zone.

Article 2 Pharmacy technicians from Macao who meet the prescribed conditions and have been granted record-filing in the Cooperation Zone may directly provide pharmacy services in drug retail units within the Cooperation Zone in conformity with their certificates of qualification as a medical professional of Macao.

For the purposes of these Regulations, the term "pharmacy technicians from

Macao" means dispensers, traditional Chinese medicine pharmacists, traditional Chinese medicine practitioners and pharmacy technicians who hold a valid certificate of qualification as a medical professional of Macao.

Article 3 A pharmacy technician from Macao who directly provides services in a drug retail unit in the Cooperation Zone shall meet all of the following conditions:

- (1) Is a Macao resident;
- (2) Holds a valid certificate of qualification as a medical professional of Macao;
- (3) Is a dispenser, traditional Chinese medicine pharmacist, traditional Chinese medicine practitioner or pharmacy technician included in Macao's Professional Qualification and Practice Registration System for Medical Professionals;
- (4) Has been trained and passed the assessment by the Drug Supervision and Administration Department of the Cooperation Zone;
- (5) Is not otherwise unfit to perform pharmacy services as defined by the State.

Article 4 A pharmacy technician from Macao who directly provides services in the Cooperation Zone shall be employed by a drug retail unit with a drug business license in the Cooperation Zone, or apply for a drug retail license to engage in drug retail services.

Article 5 Before directly providing services in the Cooperation Zone, a pharmacy technician from Macao shall apply for record-filing with the Drug Supervision and Administration Department of the Cooperation Zone.

The applicant shall submit the materials to be filed for record in accordance with the record-filing measures, which shall be formulated separately by the Drug Supervision and Administration Department of the Cooperation Zone.

If the applicant meets the conditions for record-filing, the Drug Supervision and Administration Department of the Cooperation Zone shall grant him or her record-filing, indicate the type and duration of his/her practice, and issue a record-filing certificate. The list of applicants granted record-filing shall be published on the government affairs website of the Cooperation Zone.

Pharmacy technicians from Macao who have not been granted record-filing by the Drug Supervision and Administration Department of the Cooperation Zone shall not directly provide services in drug business units in the Cooperation Zone.

Article 6 The record is valid for three years, and may be renewed upon application by the record-holder.

During the validity period of the record, if the category of the certificate of qualification of the pharmacy technician from Macao who has been granted record-filing, the category of his/her practice, or the unit where he/she practices has

changed, he/she shall apply to the Drug Supervision and Administration Department of the Cooperation Zone for a change of the record. If no change is made as required, the original record shall automatically become invalid.

Article 7 Pharmacy technicians from Macao who have been granted record-filing shall comply with the laws, regulations, rules and standards of the Mainland on drug administration when practicing in the Cooperation Zone.

Where a pharmacy technician from Macao who has been granted record-filing conducts online sales and prescription reviews in a drug retail unit in the Cooperation Zone, he/she shall comply with the relevant regulations of the Mainland, and the specific measures shall be formulated separately by the Drug Supervision and Administration Department of the Cooperation Zone.

Article 8 Where a drug retail unit in the Cooperation Zone is staffed by dispensers or traditional Chinese medicine pharmacists from Macao who have been granted record-filing by the Drug Supervision and Administration Department of the Cooperation Zone, it shall be deemed to be staffed by licensed dispensers or licensed traditional Chinese medicine pharmacists in the Mainland; where a drug retail unit in the Cooperation Zone is staffed by pharmacy technicians or traditional Chinese medicine practitioners from Macao who have been granted record-filing by the Drug Supervision and Administration Department of the Cooperation Zone, it shall be deemed to be staffed by other types of pharmacy or TCM technicians in the Mainland.

Article 9 The Drug Supervision and Administration Department of the Cooperation Zone shall provide conditions for pharmacy technicians from Macao who have been granted record-filing to receive continuing education, and include them in training.

Pharmacy technicians from Macao who have been granted record-filing shall participate in continuing education and training as required by the Drug Supervision and Administration Department of the Cooperation Zone.

Where a pharmacy technician from Macao who has been granted record-filing has earned the required credits from continuing professional development activities in Macao, the Drug Supervision and Administration Department of the Cooperation Zone shall recognize the credits.

Article 10 The Drug Supervision and Administration Department of the Cooperation Zone shall, in accordance with the relevant laws, regulations, rules and standards of the Mainland, supervise and administer the practice of pharmacy technicians from Macao who have been granted record-filing in drug retail units within the Cooperation Zone.

Article 11 Where a pharmacy technician from Macao ceases to directly provide services in a drug retail unit in the Cooperation Zone, or no longer meets the conditions for record-filing, or do not meet the requirements for continuing education, his/her record shall automatically become invalid, and he/she or the unit where he/she practices shall apply to the Drug Supervision and Administration Department of the Cooperation Zone for cancellation of his/her record in a timely manner.

Article 12 Where a pharmacy technician from Macao who has not been granted record-filing by the Drug Supervision and Administration Department of the Cooperation Zone directly provides pharmacy services in a drug retail unit in the Cooperation Zone, or a pharmacy technician from Macao who has been granted record-filing directly provides pharmacy services beyond the stated category or duration of practice, the relevant competent authority of the Cooperation Zone shall not recognize such provision of pharmacy services and punish him or her in accordance with the relevant regulations of the Mainland for providing pharmacy services without obtaining the appropriate qualifications.

Article 13 Where a pharmacy technician from Macao who has been granted record-filing shall have his/her practicing certificate revoked according to law, or shall be prohibited from practicing or denied registration within a specific period of time for violating any law, regulation or rule of the Mainland in his/her practice activities, the Drug Supervision and Administration Department of the Cooperation Zone shall revoke his/her record, and shall no longer accept any application for record-filing from the person within the period of time stipulated by the law, regulation or rule of the Mainland during which he/she is prohibited from practicing or denied registration.

Where a pharmacy technician from Macao who has been granted record-filing has cancelled his/her record or has had his/her record revoked, the Drug Supervision and Administration Department of the Cooperation Zone shall publish the relevant information on the government affairs website of the Cooperation Zone.

Article 14 These Regulations shall come into force on August 1, 2023.