

### Checklist (3)

1. This checklist is applicable to Group III registration only.
2. The applicant is required to submit this checklist with the relevant documents listed below.
3. Please tick (☑) in the appropriate box to indicate the documents submitted.

- Completed 「 Application Form for Registration of Proprietary Chinese Medicines 」
- Application fee (a crossed cheque made payable to “The Government of the Hong Kong Special Administrative Region”)
- Personal information of the person-in-charge of the company
- Documentary proofs of manufacture or sales history of the product
- Copy of manufacturing authorization issued by the country of origin (if applicable)
- Copy of free sale documentation issued by the country of origin (if applicable)
- Product sample and prototype sales pack
- Label which has complied to the legal requirements
- Package insert which has complied to the legal requirements
- Master formula (names and quantities of all active ingredients and excipients)
- Heavy metals and toxic element test report
- Pesticide residues test report
- Microbial limit test report
- Acute toxicity test report
- Long-term toxicity test report
- Local toxicity test report (only applicable to a pCm to be administered on the skin or mucus membranes)
- Mutagenicity test report (only applicable to pCm which contains newly discovered Chinese herb, ingredients with cytotoxic, known carcinogenic or mutagenic effects)
- Carcinogenicity test report (only applicable to a pCm which contains newly discovered Chinese herb, ingredients with known carcinogenic/mutagenic effects or found positive in mutagenicity test)
- Reproductive toxicity report (only applicable to a pCm which contains newly discovered Chinese herb, relates to pregnancy, proven to have toxic effects on reproductive system in other toxicity test, or tested positive in mutagenicity test)
- Summary report on all product safety documents
- Interpretation and principle of formulating a prescription (submission of this document can be exempted for single Chinese medicine granules)
- Reference materials on all product efficacy
- Principle pharmacodynamic study reports
- General pharmacological study reports (for a pCm with altered route of administration, altered dose form, or with new additional indications, submission of this report can be exempted)
- Clinical trial protocol and summary report
- Summary report on product efficacy documents
- Manufacturing method
- Physiochemical properties of crude drugs
- Product specification, method and certificate of analysis **【For pCm that is manufactured, or sold on/before 19 December 2003, the applicant can submit the standard, test method and result on assay of the product upon the application for renewal of such registration.】**
- Real-time stability test report **【For pCm that is manufactured, or sold on/before 19 December 2003, the applicant can submit the test report upon the application for renewal of such registration.】**
- Accelerated stability test report (if available)