

### 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 (x) in the appropriate box to indicate the documents submitted.

- Completed 「 Application Form for Registration of Proprietary Chinese Medicines 」
- 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
- Physicochemical 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)