

Transitional registration checklist (C)
【Documents to be submitted within 5 years after the deadline for application of transitional registration】

1. This checklist is applicable to proprietary Chinese medicine that is transitionally registered.
2. For the holder of a 「Notice of transitional registration of proprietary Chinese medicine」, he/she is required to complete the transitional registration number in the box below and to submit this checklist with the relevant listed documents within 5 years after the deadline for application of transitional registration.
3. Please tick (☑) in the appropriate box to indicate the documents to be submitted.

Transitional Registration Number of the pCm: HKP-

Registration Group			Documents to be submitted
Group I	Group II	Group III	
	<input type="checkbox"/>	<input type="checkbox"/>	Acute toxicity test report
	<input type="checkbox"/>	<input type="checkbox"/>	Long-term toxicity test report
	<input type="checkbox"/>	<input type="checkbox"/>	Local toxicity test report (only applicable to the pCm to be administered on the skin or mucus membranes)
	<input type="checkbox"/>	<input type="checkbox"/>	Mutagenicity test report (only applicable to a pCm which contains newly discovered Chinese herb, ingredients with cytotoxic or known carcinogenic/mutagenic effects)
	<input type="checkbox"/>	<input type="checkbox"/>	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)
	<input type="checkbox"/>	<input type="checkbox"/>	Reproductive toxicity report (only applicable to a pCm which contains newly discovered Chinese herb, relates to pregnancy, is proven to have toxic effects on reproductive system in other toxicity test, or found positive in mutagenicity test)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Summary report on all product safety documents
		<input type="checkbox"/>	Principle pharmacodynamic study reports
		<input type="checkbox"/>	General pharmacological studies report (for a pCm with altered route of administration, altered dose form, or with new additional indications, submission of this report can be exempted)
		<input type="checkbox"/>	Clinical trial protocol and its summary report
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Summary report on all product efficacy documents
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Product specification, method and certificate of analysis
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	*General stability test report / accelerated stability test report (*delete as appropriate)
	<input type="checkbox"/>	<input type="checkbox"/>	Real-time stability test report

Notes: If an applicant fails to submit the required documents within 5 years after the deadline for application of transitional registration, the transitional registration of the pCm will be revoked.