MOH/P/BPTK/24.26(GU) - e

Ministry of Health Malaysia

GUIDELINES FOR

LISTING AND DELISTING OF TRADITIONAL AND COMPLEMENTARY MEDICINE PRODUCTS IN THE MINISTRY OF HEALTH HEALTHCARE FACILITIES

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Traditional and Complementary Medicine Division
Ministry of Health Malaysia

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Available at the following website: http://www.moh.gov.my/tcm

This guideline shall be read in conjunction with the applicable laws, regulations, and relevant policies or guidelines currently in force, including but not limited to those listed in the references section.

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ABBREVIATION AND ACRONYMS

ADR	Adverse Drug Reaction
DCA	Drug Control Authority
GMP	Good Manufacturing Practices
ICD-11	International Classification of Diseases 11th Revision
MOH	Ministry of Health
NPRA	National Pharmaceutical Regulatory Agency
TM	Traditional Medicine
TCM	Traditional Chinese Medicine
TMM	Traditional Malay Medicine
TIM	Traditional Indian Medicine
T&CM	Traditional and Complementary Medicine

GLOSSARY

Concentration ratios	The ratio of concentrated extract to excipients of the herbal granules[1].
Herbal Granule	Processed from decocted herb or formula that contain carrier/ excipient such as potato starch or raw herb powder[2]
International Classification of Diseases 11th Revision Traditional Medicine Module	Referring to the code(s) for Traditional Medicine Conditions under the International Classification of Diseases 11th Revision
Ministry of Health Traditional and Complementary Medicine Formulary	A list of traditional and complementary medicine products available at Traditional and Complementary Medicine Units, Ministry of Health hospitals and its related information.
Traditional Medicine	Traditional medicine has a long history. It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.[3]
Traditional and Complementary Medicine	A form of health-related practice designed to prevent, treat or manage ailment or illness or preserve the mental and physical well-being of an individual and includes such practices as traditional Malay medicine, Islamic medical practice, homeopathy, and complementary therapies, but excludes medical and dental practices used by a medical and dental practitioner respectively.[4]
Traditional and Complementary Medicine Product	The term “traditional and complementary medicine product” used in this document refers to any forms of medicine/ drug used in traditional and complementary medicine practices, encompassing natural products, cosmetic products, herbs and etc.
Traditional Chinese Medicine	Traditional Chinese Medicine is a valuable accumulation of long-term experiences in understanding life, maintaining health, and overcoming diseases based on the culture and practices of the Chinese people. TCM is divided into several sub-areas based on the methods of treatment, including Chinese herbs, acupuncture and moxibustion, Chinese cupping and tuina.[5]
Traditional Indian Medicine	Traditional Indian Medicine is based on the Indian knowledge that is inherited and passed down to generations. TIM comprise a few sub-fields based on different practices including ayurveda, siddha, unani, and yoga and naturopathy.[6]
Traditional Malay Medicine	Traditional Malay Medicine is a heritage of knowledge, skills and practices based on traditional theory, belief and experiences. It has a holistic approach based on the physical and spiritual elements, which include the mind, body, and spirit.[7]

INTRODUCTION

General Overview

The Ministry of Health (MOH) Traditional and Complementary Medicine (T&CM) Formulary serves as a reference document for T&CM products used in MOH healthcare facilities. It provides a list of approved T&CM products together with essential information to guide healthcare professionals in their use, including prescribing, dispensing, and counselling.

Complementing the MOH T&CM Formulary, the *Guidelines for Listing and Delisting of T&CM Products in the MOH Healthcare Facilities* provide guidance and an administrative framework for the assessment and evaluation of T&CM products intended for use in MOH healthcare facilities. The guidelines outline the requirements and evaluation processes for listing and delisting T&CM products in the MOH T&CM Formulary and clarify the roles and responsibilities of the committees and stakeholders involved.

The development of this document was led by the MOH T&CM Formulary Development Committee, comprising representatives from the T&CM Division, Pharmacy Practice and Development Division, National Pharmaceutical Regulatory Agency, and T&CM Units in MOH hospitals. Inputs from experts, academicians, manufacturers, and suppliers were obtained through engagement sessions, followed by review by the MOH T&CM Formulary Technical Committee and approval by MOH top management.

Scope

This document serves as a guideline for the T&CM listing process and applies to all healthcare professionals and T&CM/pharmaceutical industries involved in the selection, procurement and use of T&CM products in T&CM Units within MOH healthcare facilities.

Main Objective

To provide guidance for assessing, evaluating, listing and delisting T&CM products in the MOH T&CM Formulary for use in T&CM Units within MOH healthcare facilities, ensuring safety, quality and rational use.

Specific Objectives

(i) To standardise the evaluation process, including the requirements and evidence needed for the listing and delisting of T&CM products in MOH healthcare facilities.
(ii) To promote the rational selection, use, and acquisition of T&CM products in alignment with current national budgetary considerations.
(iii) To ensure that T&CM products used in MOH healthcare facilities meet appropriate standards of safety and quality.

GOVERNANCE STRUCTURE

This section describes the roles and responsibilities of the Secretariat, the Technical Committee and the External Review Panel in managing the MOH T&CM Formulary to support transparent, systematic, and evidence-based evaluation, listing, and delisting of T&CM products in MOH healthcare facilities.

1. Secretariat

The T&CM Division, MOH Malaysia acts as the secretariat of the MOH T&CM Formulary, responsible for coordinating and overseeing the matters related to the MOH T&CM Formulary.

Roles and Responsibilities

(i) To process applications for the listing and delisting of T&CM products in the MOH T&CM Formulary, based on approved mechanism.
(ii) To seek technical input and suggestion for improvement from the Technical Committee for the MOH T&CM Formulary and the listing and delisting mechanism of T&CM products.
(iii) To prepare an annual report on conducted activities, including amendments to the MOH T&CM Formulary, the number of meetings, and other activities related to the MOH T&CM Formulary.
(iv) To facilitate meetings of the Technical Committee for the MOH T&CM Formulary relevant product assessment and forward recommendation of the meeting to the Director General of Health for final decision.
(v) To update the MOH T&CM Formulary based on the decisions made by the Director General of Health.
(vi) To carry out assigned tasks according to current needs.

2. Technical Committee

The Technical Committee of the MOH T&CM Formulary consists of experts with relevant knowledge and expertise in T&CM, pharmaceuticals, and related fields to ensure comprehensive and evidence-based evaluation of T&CM products used in the T&CM Unit, MOH healthcare facilities.

Chairperson	:	Director of T&CM Division / Representative	
Members	:	T&CM Division	1 member
		Pharmacy Practice and Development Division	1 member
		National Pharmaceutical Regulatory Agency	1 member
		Head of T&CM Unit/ Representative from National Cancer Institute	1 member
		Head of T&CM Unit/ Representative from Cheras Rehabilitation Hospital	1 member

Roles and Responsibilities

(i) To conduct regular assessments or updates of the MOH T&CM Formulary as required.
(ii) To appoint the External Review Panel and seek its input, where necessary, to support the assessment of T&CM products.
(iii) To invite relevant stakeholders or technical officers to participate in meetings or provide technical input, where necessary.
(iv) To review and make recommendation to Director General of Health for the listing and delisting of T&CM products.
(v) To identify current issues pertaining to the MOH T&CM Formulary in MOH hospitals and propose suitable solutions, plans, or policies to be presented to the MOH top management, as necessary.
(vi) To perform tasks assigned to them based on project requirements and directives from the Chairperson of the Committee.

3. External Review Panel

The External Review Panel comprises independent local or international experts in the traditional medicine field who provide specialised input to support the Technical Committee, ensuring that evaluations are guided by recognised traditional medicine principles, relevant evidence, and sound expert judgement. Members of the Panel are appointed by the Chairperson of the Technical Committee and shall operate in accordance with the terms of reference specified in their respective appointment letters.

TYPES OF SUBMISSION

These Guidelines apply to the following types of submissions under the MOH T&CM Formulary:

T&CM Product Listing Submission (T1)
Proposals to add new T&CM products to the MOH T&CM Formulary. It also encompasses modifications to existing products within the formulary, including adding new indications and amending formulations.

T1 submissions are categorised by traditional medicine practices:

- T1 (A) covers Traditional Chinese Medicine (TCM), including herbal medicines;
- T1 (B) covers Traditional Indian Medicine (TIM), which includes Ayurveda, Siddha, Unani products, and related remedies; and
- T1 (C) covers on Traditional Malay Medicine (TMM), focusing on products like massage oils.

T&CM Product De-Listing Submission (T2)
Proposals to remove approved T&CM products or specific indications from the MOH T&CM Formulary. This may be necessary if a product is no longer clinically or economically suitable, or if there are safety concerns.

T&CM Product Information Update (T3)
Proposals to update information of T&CM product listed in MOH T&CM Formulary.

The types of dossier and the corresponding eligible applicants:

Type of dossier/ form	Details	Applicant
T1 (A)	To list products for TCM practice use	MOH
T1 (B)	To list products for TIM practice use	
T1 (C)	To list products for TMM practice use	
T2	To delist approved products/ indication	MOH
T3	To amend/ update information of listed product	MOH/ T&CM/ Pharmaceutical industries

Contact Details for the MOH T&CM Formulary Secretariat
All complete dossiers and relevant supporting documents, in the latest prescribed format where applicable, shall be submitted to the Secretariat at the address below or via email to tcm@moh.gov.my

Secretariat of the Ministry of Health Traditional and Complementary Medicine Formulary
Traditional and Complementary Medicine Division
Ministry of Health Malaysia
Block E, Jalan Cenderasari, 50590 Kuala Lumpur

SECTION A
GENERAL INSTRUCTION FOR T&CM PRODUCT LISTING (T1)

This section provides guidance on the T1 submission process for listing T&CM products in the MOH T&CM Formulary, including proposals to modify existing listed products, such as the addition of new indications or amendments to product formulations.

1. Eligibility Criteria to Submit Dossier for Product Listing

Applicants

Applications for listing of T&CM products in the MOH T&CM Formulary shall be submitted by MOH officers. Submissions shall be based on service requirements, clinical needs, safety considerations, and operational relevance within MOH healthcare facilities.

T&CM Products

The types of T&CM products eligible for consideration under the MOH T&CM Formulary include:

(i) T&CM products categorised as natural products that are registered with the Drug Control Authority (DCA) in Malaysia;
(ii) T&CM products categorised as cosmetic products that are notified with the National Pharmaceutical Regulatory Agency (NPRA) under the Control of Drugs and Cosmetics Regulations 1984; and
(iii) T&CM preparations that are exempted from registration or notification requirements by MOH authorities, such as extemporaneous preparations using single herbs, where applicable.

2. General Instruction for T1 Dossier Preparation

All applications shall be submitted to the Secretariat using the MOH T&CM Formulary Dossier Submission Request Form (**Appendix 1**), together with a complete dossier and relevant supporting documents, where applicable. Each application must be endorsed by the Head of the Department/ Institution, confirming the necessity of the proposed application.

A complete dossier, including all required supporting documents and evidence, shall be submitted for the listing of new T&CM products or for proposed amendments to indications or formulations of existing listed products. Applicants shall use the prescribed template forms according to the relevant type of practice and comply with the instructions provided in each form.

The dossier form consists of three (3) sections:

Section	Details
Section 1: Product Information	This section shall include comprehensive product details, including product particulars and relevant clinical and pharmacological information supported by reliable references. Information on marketed products shall be obtained from the supplier or company to confirm product availability and pricing. Additional product-related information, such as package inserts or labelling, shall also be provided where applicable.
Section 2: Rationale for Application and Comparators	Applicants shall provide a clear justification for the proposed listing, amendment, or update of the product in the formulary. This shall include the clinical or service-related rationale and, where applicable, cost comparisons with existing products or therapeutic alternatives.
Section 3: Supporting Evidence (Quality, Safety and Clinical Usage)	Applicants shall submit relevant evidence to support the quality, safety, and clinical use of the product. This may include clinical studies, peer-reviewed publications, quality certifications, and safety data. All supporting evidence shall be directly relevant to the application and aligned with the specific purpose of listing or amendment.

For the purpose of evaluating product availability and conducting cost assessment and comparison, relevant information shall be obtained from the supplier or company to reflect the current market status of the product. This includes product-related information and pricing details. Accordingly, the Product Price Declaration Form (**Appendix 5**) shall be completed by the supplier or company to declare the price of the T&CM product for reference during the evaluation process and for consideration for listing in the MOH T&CM Formulary. The completed declaration form shall be submitted by the MOH applicant as part of the dossier.

All dossiers must be accompanied by a completed dossier checklist. Where required information is unavailable, a brief justification shall be provided. Only complete and satisfactory submissions will be accepted for processing. Incomplete or unsatisfactory applications may be returned to the applicant.

The following documents and appendices must be included in the dossier, depending on the T&CM practice:

No.	Documents	Appendices for Each Type of Dossier by T&CM Practices		
		T1(A)	T1(B)	T1(C)
1	Dossier Checklist	2(i)	3(i)	4(i)
2	Dossier Forms	2(ii)	3(ii)	4(ii)
3	Product Price Declaration Form	5		
4	Cost Comparison	6		

T1(A): products for TCM practice use; T1(B): products for TIM practice use; T1(C): products for TMM practice use

Upon receipt of a complete submission, the Secretariat shall undertake internal information gathering as part of the evaluation process. This may include seeking additional information, such as safety data from relevant MOH authorities, or obtaining justifications from the relevant T&CM Units to substantiate the necessity of the T&CM product or the proposed amendments.

3. Technical Evaluation and Approval

Evaluation Process and Technical Review

The Secretariat shall conduct an initial administrative and completeness screening of the submitted dossier within **7 working days** of receipt. Upon confirmation of a complete dossier, an evaluation period of up to **12 weeks** shall be allocated for review by the Technical Committee. Where specialised expertise is required, the Technical Committee may seek input from the External Review Panel. Based on the evaluation, the Technical Committee shall formulate recommendations for submission to the Director General of Health.

The Secretariat reserves the right to determine the number of dossiers reviewed within a given period, considering the evaluation timeline and the overall capacity of the Technical Committee.

Decision and Outcome

The Director General of Health shall consider the recommendations submitted by the Technical Committee and may approve, defer, reject, or impose conditions on the application.

The Secretariat shall communicate the decision to the submitting MOH officer through email and/or official correspondence and update the MOH T&CM Formulary accordingly. Where relevant, the outcome of the application may also be shared with the Secretariat of the MOH Drug Formulary for information.

Confidentiality

All information and documents submitted to the Secretariat shall be treated as confidential and used solely for the purpose of evaluation and decision-making under the MOH T&CM Formulary.

Withdrawal of Dossier

Applicants may withdraw their dossier at any stage of the evaluation process by submitting a written request to the Secretariat. Upon withdrawal, the application shall be considered closed. Any subsequent submission shall be treated as a new application.

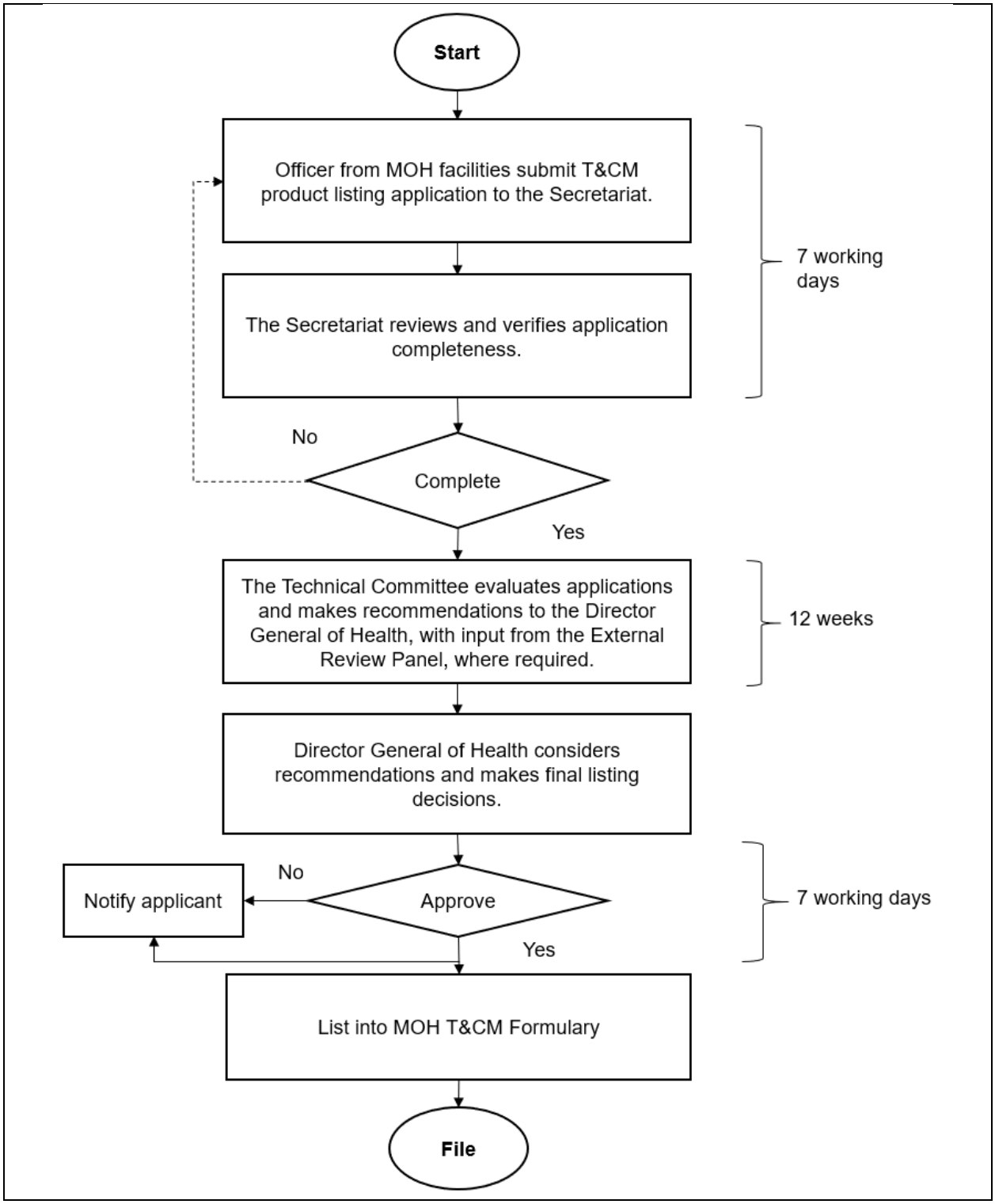
Resubmission

Applications that are not approved may be resubmitted after addressing the grounds for non-approval, such as updated evidence, revised cost considerations, or additional safety information. A minimum interval of **12 weeks** shall apply before resubmission. Where a resubmission is again not approved, any subsequent resubmission shall only be considered after a minimum period of **6 months.**

Dossier Submission Processing Fees

No processing fee shall be imposed for submission or resubmission of applications, until further notice.

4. Workflow of Listing T&CM Products (T1 Submission)



SECTION B
GENERAL INSTRUCTION FOR T&CM PRODUCT DE-LISTING (T2)

This section provides guidance on the T2 submission process for the de-listing of T&CM products or approved indications from the MOH T&CM Formulary.

1. Dossier Submission and Proposal for Delisting

All applications for product de-listing shall be submitted to the Secretariat using the MOH T&CM Formulary Dossier Submission Request Form (**Appendix 1**), together with a complete Dossier T2 (**Appendix 7**) and relevant supporting documents, where applicable. Only complete submissions that comply with the requirements set out in these Guidelines will be accepted for processing.

Any T&CM product or approved indication listed in the MOH T&CM Formulary may be proposed for de-listing. Reasons for de-listing may include, but are not limited to:

- Withdrawal from the global or local market;
- No or low usage of the product;
- Changes in policy or practice;
- Emergency safety concerns or adverse findings.

Each submission must be supported by relevant documentation, including clear identification of the product or indication proposed for de-listing, a justification and rationale for the proposed de-listing, and information on alternative products available in the MOH T&CM Formulary for the same indication(s), where applicable. All de-listing proposals must be endorsed by the Head of the Department/ Institution, confirming the necessity and appropriateness of the request.

2. Technical Evaluation and Approval

Evaluation Process and Technical Review
The Secretariat shall conduct an initial administrative and completeness screening of the submitted dossier within **7 working days** of receipt. Complete submissions shall be forwarded to the Technical Committee for evaluation.

The Technical Committee shall complete the evaluation within **12 weeks**. Where specialised expertise is required, the Committee may seek input from the External Review Panel with relevant expertise in the traditional medicine field.

Decision and Outcome

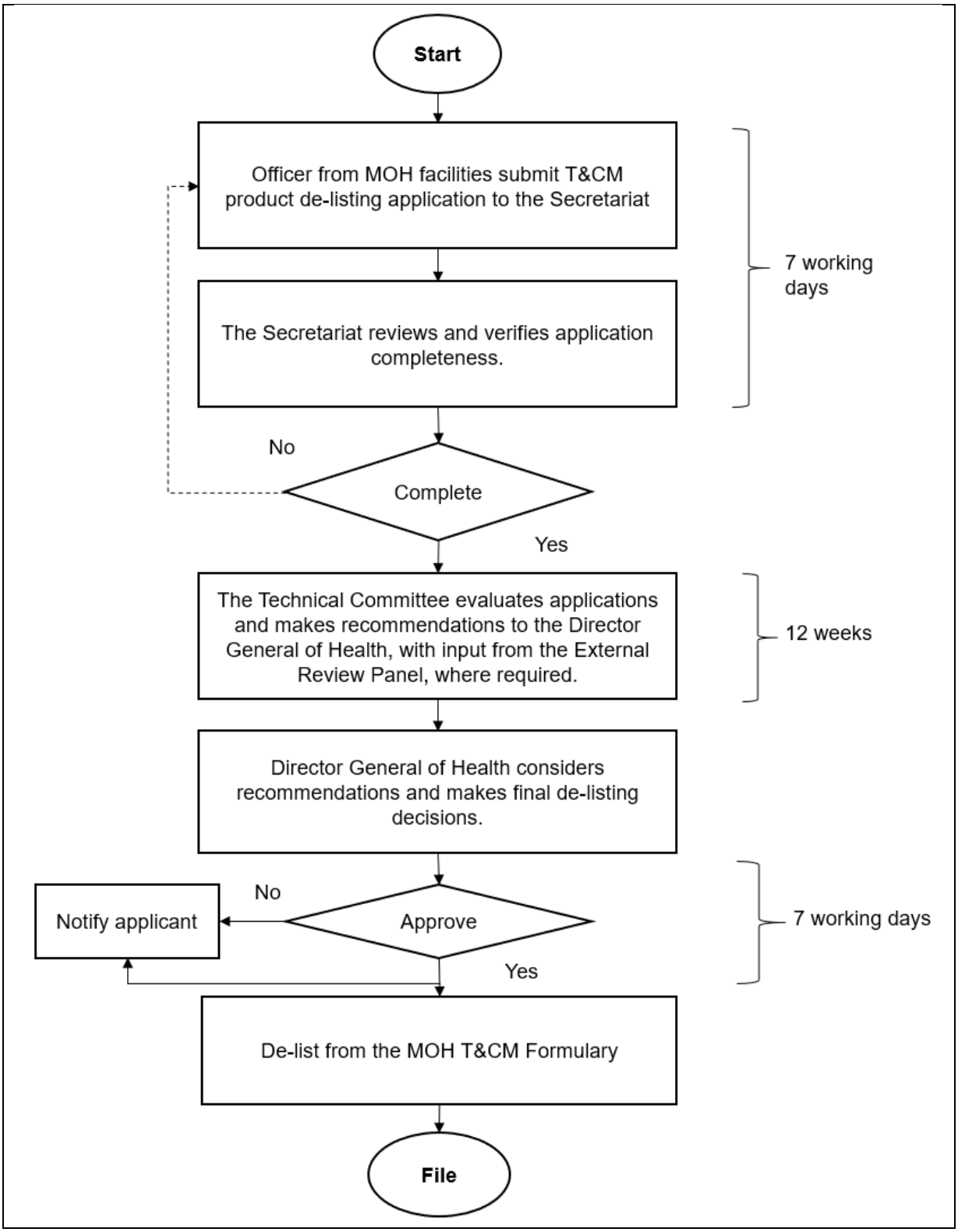
Based on the evaluation, the Technical Committee shall formulate recommendations for submission to the Director General of Health, who retains the authority to approve, defer, or reject the proposed de-listing.

The Secretariat shall communicate the outcome of the decision to the applicant through email and/or official correspondence within **7 working days** of the decision.

Re-Listing of Delisted Products

Requests to relist a delisted product must be strongly justified with a written request submitted to the Secretariat. Where applicable, the Secretariat may require the submission of a new dossier for re-listing. The scope and requirements for re-listing shall be determined on a case-by-case basis, considering updated evidence, safety information, service needs, and policy considerations.

3. Workflow of De-Listing T&CM Products (T2 Submission)



SECTION C: T&CM PRODUCT INFORMATION UPDATE (T3)

This section provides guidance on the T3 submission process for updating information of T&CM products listed in the MOH T&CM Formulary.

1. Submission of Proposal

Proposals to update information of T&CM products listed in the MOH T&CM Formulary may be submitted by MOH healthcare personnel or representatives from the T&CM or pharmaceutical industry. Submissions shall be made by completing the Information Update Request Form T3 (**Appendix 8**) and submitting it together with the MOH T&CM Formulary Dossier Submission Request Form (**Appendix 1**) to the Secretariat. Only complete submissions that comply with the requirements set out in these Guidelines will be accepted for processing.

Information proposed for update may include, but is not limited to:

- Herb–herb interactions and herb–drug interactions;
- Precautions and contraindications;
- Adverse drug reactions (ADR);
- Dosage and administration information.

Each proposal must be accompanied by relevant supporting documents, such as DCA-approved product information leaflets, updated clinical guidelines, published literature, or other relevant references to substantiate the proposed update.

2. Technical Evaluation and Approval

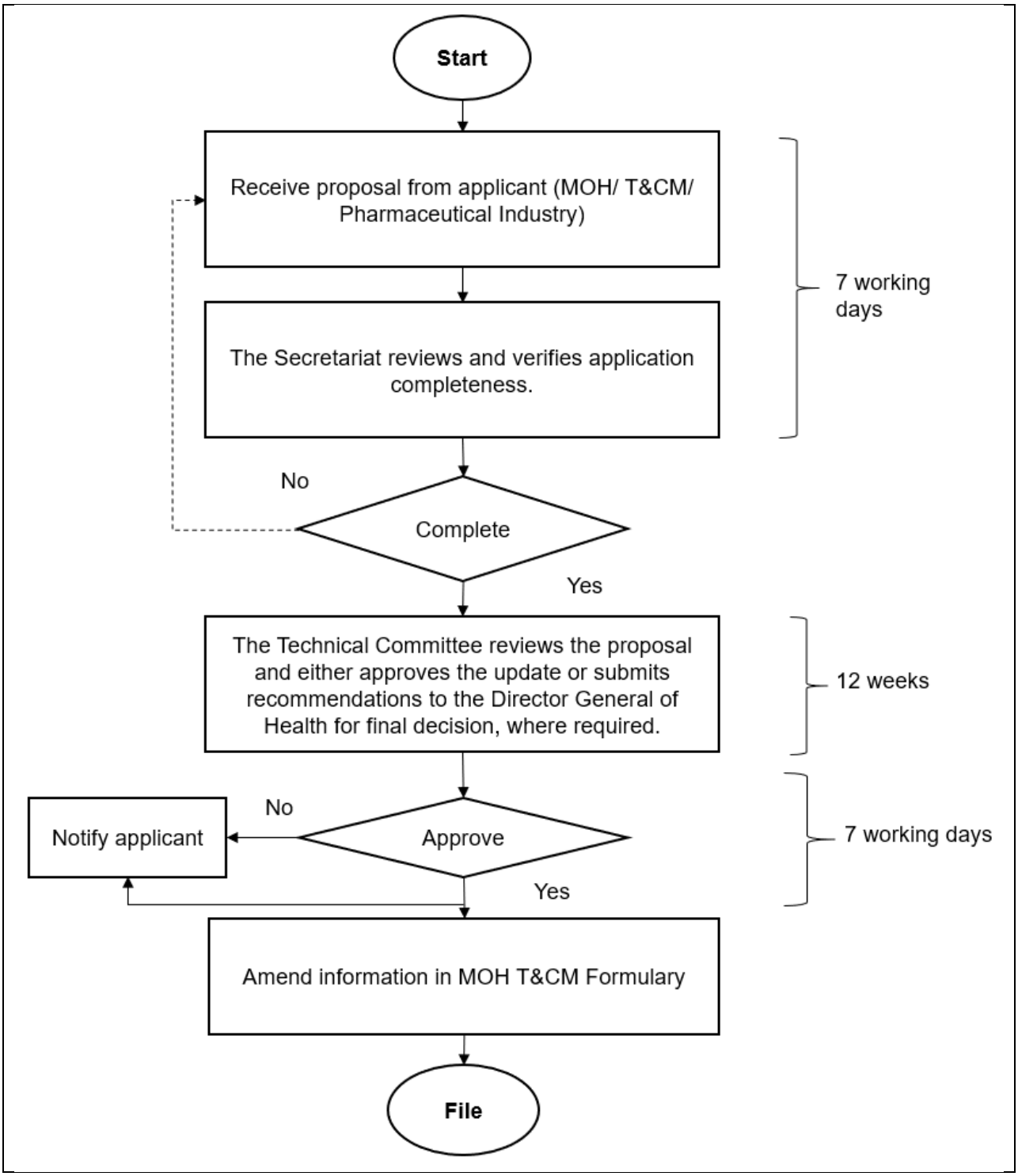
The Secretariat shall conduct an initial administrative and completeness screening of the submitted dossier within **7 working days** of receipt. Complete submissions shall be forwarded to the Technical Committee for evaluation, which shall be completed within **12 weeks**.

Where specialised expertise is required, the Technical Committee may seek input from the External Review Panel with relevant expertise in the traditional medicine field.

Based on the evaluation, the Technical Committee shall endorse the proposed update or provide recommendations for revision. Where the proposed update involves policy, safety, or significant clinical implications, the recommendation shall be submitted to the Director General of Health for final decision.

Upon approval, the Secretariat shall update the MOH T&CM Formulary accordingly. The applicant shall be informed of the outcome via email or official correspondence.

3. Workflow for Information Update of T&CM Products (T3)



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4. Laws of Malaysia, 2016. Traditional and Complementary Medicine Act 2016 (Act 775). Kuala Lumpur: Percetakan Nasional Malaysia Berhad

5. Traditional and Complementary Medicine Division, Ministry of Health, 2021. *Garis Panduan Pendaftaran Pengamal Perubatan Tradisional dan Komplementari Tempatan - Perubatan Tradisional Cina.*

6. Traditional and Complementary Medicine Division, Ministry of Health*, 2021. Garis Panduan Pendaftaran Pengamal Perubatan Tradisional dan Komplementari Tempatan - Perubatan Tradisional India.*

7. Traditional and Complementary Medicine Division, Ministry of Health*, 2021. Garis Panduan Pendaftaran Pengamal Perubatan Tradisional dan Komplementari Tempatan - Perubatan Tradisional Melayu.*

8. Guidelines on Submission on Dossier for Listing into the Ministry of Health Medicines Formulary, 3rd Edition 2024, by Pharmacy Practice & Development Division, Ministry of Health Malaysia.

APPENDICES

APPENDIX 1
MINISTRY OF HEALTH TRADITIONAL AND COMPLEMENTARY MEDICINE FORMULARY DOSSIER SUBMISSION REQUEST FORM (T1/T2/T3)

To:
Secretariat of MOH T&CM Formulary
Traditional and Complementary Medicine (T&CM) Division
Ministry of Health (MOH) Malaysia Date:

Type of Dossier Submission	
(Please tick (/) where applicable)	Product Listing □ T1(A) for Traditional Chinese Medicine Practice □ T1(B) for Traditional Indian Medicine Practice □ T1(C) for Traditional Malay Medicine Practice
	□ T2 for Product De-Listing
	□ T3 for Information Update / Amendment
Product Details	
Generic Name	
Active Ingredients	
Indication(s) / Information Affected (if applicable):	
Brief Justification of Submission	

I hereby confirm that the relevant checklist(s), dossier(s), and supporting documents required for this submission are complete and attached in accordance with the Guidelines for Listing and Delisting of T&CM Products in the MOH Healthcare Facilities.

Details of Applicant	
Name: Designation: Unit/ Section: Deparment/ Institution: Contact No & Email Address: Signature & Stamp: Date:	
Supported by Head of Unit/ Section	**Endorsed by Head of Department**
Signature & Stamp: Date:	Signature & Stamp: Date:

APPENDIX 2
DOSSIER PREPRATION FOR T1 (A)
TRADITIONAL CHINESE MEDICINE PRACTICE

APPENDIX 2(i): CHECKLIST FOR DOSSIER T1 (A)

CHECKLIST FOR INFORMATION TO BE INCLUDED IN DOSSIER T1				
Tick (/) for the purpose of submission				
	Proposal to list new T&CM product into the MOH T&CM Formulary			
	Proposal to list new indication(s) for existing T&CM product in the MOH T&CM Formulary			
	Proposal to amend formulation for existing T&CM product in the MOH T&CM Formulary			
No.	**Details**	**Tick (/)**	**Please provide reasons if the particulars are not submitted/ completed**	**For Secretariat Use**
Section 1: Product Information				
A. Particulars				
1.	Generic name			
2.	Active ingredient and strength			
3.	Type of formulation			
4.	Dosage form			
B. Clinical & Pharmacological Information				
5.	Proposed indication(s) for the MOH T&CM Formulary			
6.	ICD-11 TM Code(s)			
7.	Recommended dosage range and administration			
8.	Propose course of treatment (duration) and repeat (if any)			
9.	Therapeutic grouping			
10.	Warning/ precaution			
11.	Contraindication			
12.	Storage condition			
13.	Interactions (Medicine/ Herbs/ Food/ Disease)			
14.	Adverse reactions			
C. Marketed Product and Related Treatment Costs				
15.	Details of Marketed Product(s)			
16.	Packaging size and price per item			
17.	Price per dosage unit			

18.	Number of dosage units administered per day or per cycle			
19.	Average duration of treatment in days or cycles per year			
20.	Total product cost per patient per year			
21.	Additional cost per patient per year			
22.	Total annual cost per patient			
Section 2: Rationale for Application and Comparators				
23.	Rationale for listing application			
24.	Details on rationale for listing application			
25.	Existing product(s) for same indication			
Section 3: Supporting Clinical Evidence (Safety, Quality and Clinical Usage)				
26.	Certificates of analysis, GMP certifications and/or Certificate of Origin/ health declarations			
27.	Information on adverse events, contraindications, precautions, and potential interactions with other medications/ post-marketing surveillance data if available.			
28.	Summary of relevant clinical studies/ journal articles/ pharmacopeia, monograph or classical reference/ treatment guidelines			
Others				
29.	T&CM Product Price Declaration Form (Appendix 5)			
30.	Cost Comparison (Appendix 6)			
31.	Sample of product (one unit only with packaging/ box), if requested			
32.	Product information leaflet			

Filled in by: *Please state applicant's name, designation, organisation, email address and contact no.*

Date:

Note:

- Incomplete documents will not be processed.
- Each application form should only pertain to one product.
- All documents must be submitted in softcopy, with hardcopies provided upon request.

FOR SECRETARIAT USE	
Dossier receipt date	
Dossier complete date	
Reference no.	
Checked by	
Comments	

APPENDIX 2(ii): DOSSIER T1 (A) FORM

Instructions

- Applicant should provide detailed information about the T&CM product for traditional Chinese medicine (TCM) practices as required in the form below.
- The information should be obtained from official reliable sources for example pharmacopeia, monograph or classic references.
- All information, references or supporting evidence submitted, if it is not written in *Bahasa Malaysia* or English, the applicant shall submit a copy in its original language and a translated copy in either Bahasa Malaysia or English.
- All applications must attach their latest packaging insert and label, where relevant.
- Sample of product should be provided upon request by the Secretariat.

Section 1: Product Information		
A. Particulars		
1.	Generic name	*Provide generic name of the product according to the classic references*
2.	Active ingredient and strength	*Provide all active ingredients of the product and strength for each ingredient according to the classic references*
3.	Type of formulation	*State the type of formulation (e.g. single herbs, formula herbs)*
4.	Dosage form	*State the dosage form (e.g. granules, tablets, capsule or oil)*
B. Clinical and Pharmacological Information		
5.	Proposed indication(s) for the MOH T&CM Formulary	*State the proposed indication(s) to be listed in the MOH T&CM Formulary. Provide references.*
6.	ICD-11 TM Code(s)	*State the ICD-11 TM code(s) corresponding to the proposed indication(s) following TCM philosophy (if applicable)*
7.	Recommended dosage range and administration	*State the dose, frequency and route of administration for the medicine. Provide references.*
	Adult dose and frequency	*(If applicable)*
	Paediatric dose and frequency	*(If applicable)*
8.	Propose course of treatment (duration) and repeat if any	*State the recommended duration of treatment and/or treatment cycle. Provide references.*
9.	Therapeutic grouping	*State the therapeutic grouping (if applicable)*
10.	Warning/ precaution	*State all warnings and precautions. Provide references.*
11.	Contraindication	*State all contraindications. Provide references.*
12.	Storage condition	*State the storage information. Provide references.*
13.	Interactions (Medicine/ Herbs/ Food/ Disease)	*State the significant interaction(s) between medicine/ herbs/ food/ disease. Provide references.*

14.	Adverse reactions	*State all adverse reactions. Provide references.*
C. Marketed Product and Related Treatment Costs		
15.	Details of Marketed Product(s)	*(to name at least one (1) example of marketed product in Malaysia)* Product Name: *State the product's trade name* Active Ingredients: *State all the active ingredients and strength of each active ingredient* Registration Holder: *State company's name and address* Manufacturer: *State company's name and address* Registration No.: *State DCA Registration no. / Notification no. of the product, and provide relevant Approval Letter/ certificate. Not compulsory for product exempted from registration* DCA Approved Indication (if applicable)*: State the DCA approved indication for DCA registered product* Concentration ratio (if applicable): *State the concentration ratio for herbal granules* Declaration of products containing animal sources (if applicable): *State the origins of the ingredients used in preparing the product (if relevant), including the scientific name and common name of the animal source, part used, and country of origin.*
16.	Packaging size and price per item (RM)	*State the nett price of the product per packaging to MOH institutions, inclusive of all fees. Submit details as required in Product Price Declaration Form (**Appendix 5**).*
17.	Price per dosage unit (RM): (a)	*State the nett price of the product per dosage unit.*
18.	Number of dosage units administered per day or per cycle (b)	*State the number (or average number) of dosage units administered per day or per cycle.*
19.	Average duration of treatment in days or cycles per year (c)	*State the average/ maximum duration of treatment in days or number of cycles per year. If the treatment is continuous for 1 year, use 365 days.*
20.	Total product cost per patient per year (d) d= a x b x c	*This can be calculated by multiplying a, b and c*
21.	Additional cost per patient per year (e)	*List all potential additional costs, if relevant. Calculate potential additional costs per patient per year. This may include cost of drug monitoring and administration, cost of additional equipment required, costs to control adverse effects etc.*
22.	Total annual cost per patient (f)	*f = (d + e)*

A cost comparison between new proposed T&CM product and existing products in the MOH T&CM Formulary that is used for the same indication should be submitted by using **Appendix 6**.

Section 2: Rationale for Application and Comparators	
A. Rational for listing application:	
Tick (/) the main reason(s) to list the product:	
	Insufficiently treated condition
	Has therapeutic advantage over an existing product(s)
	A cheaper alternative to an existing product(s)
	Complementary to existing therapies
	Improve compliance
	Others (please specify):
B. Details on rationale of the application:	
Explain in detail the rationale/ justifications to list this product or amendment for the existing product. E.g. the advantages and differences of the proposed product over the available therapies in the MOH T&CM Formulary.	
C. Existing product(s) for the same/ similar indications in MOH T&CM Formulary	
List all the existing product(s) in MOH T&CM Formulary with the same/similar indication(s). Provide product names, strengths and dosage forms.	

Section 3: Supporting Evidence (Safety, Quality and Clinical Use)	
Data	**Description**
Quality	Supporting documentation shall include certificates of analysis, such as microbial contamination tests, heavy metal contamination tests, and biomarker analyses (where applicable), as well as Good Manufacturing Practice (GMP) certification and other relevant quality-related documents. For imported T&CM products, a Certificate of Origin shall be provided. Products containing animal-derived ingredients shall also be accompanied by a health declaration or Transmissible Spongiform Encephalopathies (TSE) risk evaluation certificate, where applicable.
Safety	Information on adverse events, contraindications, precautions, and potential interactions with medicines, herbs, food, or disease states shall be provided. Relevant preclinical or clinical safety studies should be included, together with post-marketing surveillance data, where available.
Clinical Use	Evidence supporting clinical use shall include relevant traditional knowledge and ethnopharmacological evidence from reliable sources,

	such as pharmacopeia, monographs, or classical references. In addition, a summary of relevant clinical studies conducted on the T&CM product is encouraged, including randomised controlled trials, observational studies, systematic reviews, and meta-analyses.

The applicant should include supporting documents that provide evidence of the quality, safety and therapeutic use of the product for listing purposes.

APPENDIX 3
DOSSIER PREPRATION FOR T1 (B)
TRADITIONAL INDIAN MEDICINE PRACTICE

APPENDIX 3(i): CHECKLIST FOR DOSSIER T1 (B)

CHECKLIST FOR INFORMATION TO BE INCLUDED IN DOSSIER T1(B)				
Tick (/) for the purpose of submission				
	Proposal to list new T&CM product into the MOH T&CM Formulary			
	Proposal to list new indication(s) for existing T&CM product in the MOH T&CM Formulary			
	Proposal to amend formulation for existing T&CM product in the MOH T&CM Formulary			
No.	**Details**	**Tick (/)**	**Please provide reasons if the particulars are not submitted/ completed**	**For Secretariat Use**
Section 1: Product Information				
A. Particulars				
1.	Generic name			
2.	Active ingredient and strength			
3.	Type of formulation			
4.	Dosage form			
B. Clinical & Pharmacological Information				
5.	Proposed indication(s) for the MOH T&CM Formulary			
6.	ICD-11 TM Code(s)			
7.	Recommended dosage range and administration			
8.	Propose course of treatment (duration) and repeat if any			
9.	Therapeutic grouping			
10.	Warning/ precaution			
11.	Contraindication			
12.	Storage condition			
13.	Interactions (Medicine/ Herbs/ Food/ Disease)			
14.	Adverse reactions			
C. Marketed Product and Related Treatment Costs				
15.	Details of Marketed Product(s)			
16.	Packaging size and price per item			
17.	Price per dosage unit			

18.	Number of dosage units administered per day or per cycle			
19.	Average duration of treatment in days or cycles per year			
20.	Total product cost per patient per year			
21.	Additional cost per patient per year			
22.	Total annual cost per patient			
Section 2: Rationale for Application and Comparators				
23.	Rationale for listing application			
24.	Details on rationale for listing application			
25.	Existing product(s) for same indication			
Section 3: Supporting Clinical Evidence (Safety, Quality and Clinical Use)				
26.	Certificates of analysis, GMP certifications and/or Certificate of Origin/ health declarations			
27.	Information on adverse events, contraindications, precautions, and potential interactions with other medications/ post-marketing surveillance data if available.			
28.	Summary of relevant clinical studies/ journal articles/ pharmacopeia, monograph or classical reference/ treatment guidelines			
Others				
29.	T&CM Product Price Declaration Form (Appendix 5)			
30.	Cost Comparison (Appendix 6)			
31.	Sample of product (one unit only with packaging/ box) if requested			
32.	Product information leaflet			

Filled in by: *Please state applicant's name, designation, organisation, email address and contact no.*

Date:

Note:

- Incomplete documents will not be processed.
- Each application should only pertain to one product.
- All documents must be submitted in softcopy, with hardcopies provided upon request.

FOR SECRETARIAT USE	
Dossier receipt date	
Dossier complete date	
Reference no.	
Checked by	
Comments	

APPENDIX 3(ii): DOSSIER T1 (B) FORM

Instructions

- Applicant should provide detailed information about the T&CM product for traditional Indian medicine (TIM) practices as required in the form below.
- The information should be obtained from official reliable sources for example pharmacopeia, monograph or classic references.
- All information, references or supporting evidence submitted, if it is not written in *Bahasa Malaysia* or English, the applicant shall submit a copy in its original language and a translated copy in either Bahasa Malaysia or English.
- All applications must attach their latest packaging insert and label, where relevant.
- Sample of product should be provided upon request by the Secretariat.

Section 1: Product Information		
A. Particulars		
1.	Generic name	*Provide full generic name of the product according to the classic references*
2.	Active ingredient and strength	*Provide all active ingredients of the product and strength for each ingredient according to the classic references*
3.	Type of formulation	*State the type of formulation (e.g. single herbs, formula herbs, mixed ingredient)*
4.	Dosage form	*State the dosage form (e.g. granules, tablets, capsule or oil)*
B. Clinical and Pharmacological Information		
5.	Proposed indication(s) for the MOH T&CM Formulary	*State the proposed indication(s) to be listed in the MOH T&CM Formulary. Provide references.*
6.	ICD-11 TM Code(s)	*State the ICD-11 TM code(s) corresponding to the proposed indication(s) following TIM philosophy (if applicable)*
7.	Recommended dosage range and administration	*State the dose, frequency and route of administration for the product. Provide references.*
	Adult dose and frequency	*(If applicable)*
	Paediatric dose and frequency	*(If applicable)*
8.	Propose course of treatment (duration) and repeat if any	*State the recommended duration of treatment and/or treatment cycle. Provide references.*
9.	Therapeutic grouping	*State the therapeutic grouping (if applicable)*
10.	Warning/ precaution	*State all warnings and precautions. Provide references.*
11.	Contraindication	*State all contraindications. Provide references.*
12.	Storage condition	*State the storage information. Provide references.*
13.	Interactions (Medicine/ Herbs/ Food/ Disease)	*State the significant interaction(s) between medicine/ herbs/ food/ disease. Provide references.*

14.	Adverse reactions	*State all adverse reactions. Provide references.*
C. Marketed Product and Related Treatment Costs		
15.	Details of Marketed Product(s)	*(to name at least one (1) example of marketed product in Malaysia)* Product Name: *State the product's trade name* Active Ingredients: *State all the active ingredients and strength of each active ingredient* Registration Holder: *State company's name and address* Manufacturer: *State company's name and address* Registration No.: *State DCA Registration no. / Notification no. of the product, and provide relevant Approval Letter/ certificate. Not compulsory for product exempted from registration* DCA Approved Indication (if applicable)*: State the DCA approved indication for DCA registered product* Declaration of products containing animal sources (if applicable): *State the origins of the ingredients used in preparing the product (if relevant), including the scientific name and common name of the animal source, part used, and country of origin.*
16.	Packaging size and price per item (RM)	*State the nett price of the product per packaging to MOH institutions, inclusive of all fees. Submit details as required in Product Price Declaration Form (**Appendix 5**).*
17.	Price per dosage unit (RM): (a)	*State the nett price to MOH institutions, inclusive of all fees.*
18.	Number of dosage units administered per day or per cycle (b)	*State the number (or average number) of dosage units administered per day or per cycle.*
19.	Average duration of treatment in days or cycles per year (c)	*State the average/ maximum duration of treatment in days or number of cycles per year. If the treatment is continuous for 1 year, use 365 days.*
20.	Total product cost per patient per year (d) d= a x b x c	*This can be calculated by multiplying a, b and c*
21.	Additional cost per patient per year (e)	*List all potential additional costs, if relevant. Calculate potential additional costs per patient per year. This may include cost of drug monitoring and administration, cost of additional equipment required, costs to control adverse effects etc.*
22.	Total annual cost per patient (f)	*f = (d + e)*

A cost comparison between new proposed T&CM product and existing products that is used for the same indication should be submitted by using **Appendix 6**.

Section 2: Rationale for Application and Comparators	
A. Rational for listing application:	
Tick (/) the main reason(s) to list the product:	
	Insufficiently treated condition
	Has therapeutic advantage over an existing product(s)
	A cheaper alternative to an existing product(s)
	Complementary to existing therapies
	Improve compliance
	Others (please specify below)
B. Details on rationale of the application:	
Explain in detail the rationale/ justifications to list this product or amendment for the existing product. E.g. the advantages and differences of the proposed product over the available therapies in the MOH T&CM Formulary.	
C. Existing product(s) for the same/ similar indications in MOH T&CM Formulary	
List all the existing product(s) in MOH T&CM Formulary with the same/similar indication(s). Provide product names, strengths and dosage forms.	

Section 3: Supporting Evidence (Safety, Quality and Clinical Use)	
Data	**Description**
Quality	Supporting documentation shall include certificates of analysis, such as microbial contamination tests, heavy metal contamination tests, and biomarker analyses (where applicable), as well as Good Manufacturing Practice (GMP) certification and other relevant quality-related documents. For imported T&CM products, a Certificate of Origin shall be provided. Products containing animal-derived ingredients shall also be accompanied by a health declaration or Transmissible Spongiform Encephalopathies (TSE) risk evaluation certificate, where applicable.
Safety	Information on adverse events, contraindications, precautions, and potential interactions with medicines, herbs, food, or disease states shall be provided. Relevant preclinical or clinical safety studies should be included, together with post-marketing surveillance data, where available.
Clinical Use	Evidence supporting clinical use shall include relevant traditional knowledge and ethnopharmacological evidence from reliable sources,

	such as pharmacopeia, monographs, or classical references. In addition, a summary of relevant clinical studies conducted on the T&CM product is encouraged, including randomised controlled trials, observational studies, systematic reviews, and meta-analyses.

The applicant should include supporting documents that provide evidence of the quality, safety and therapeutic use of the product for listing purposes.

APPENDIX 4
DOSSIER PREPRATION FOR T1 (C)
TRADITIONAL MALAY MEDICINE PRACTICE

APPENDIX 4(i): CHECKLIST FOR DOSSIER T1 (C)

CHECKLIST FOR INFORMATION TO BE INCLUDED IN DOSSIER T1(C)				
Tick (/) for the purpose of submission				
	Proposal to list new T&CM product into the MOH T&CM Formulary			
	Proposal to list new indication(s) for existing T&CM product in the MOH T&CM Formulary			
	Proposal to amend formulation for existing T&CM product in the MOH T&CM Formulary			
No.	**Details**	**Tick (/)**	**Please provide reasons if the particulars are not submitted/ completed**	**For Secretariat Use**
Section 1: Product Information				
A. Particulars				
1.	Generic name			
2.	Active ingredient and strength			
3.	Type of formulation			
4.	Dosage Form			
B. Clinical & Pharmacological Information				
5.	Proposed indication(s) for the MOH T&CM Formulary			
6.	Propose course of treatment (duration) and repeat if any			
7.	Warning/ Precaution			
8.	Contraindication			
9.	Storage condition			
10.	Adverse reactions			
C. Marketed Product and Related Treatment Costs				
11.	Details of Marketed Product(s)			
12.	Packaging size and price per item			
13.	Price per dosage unit			
14.	Number of dosage units administered per day or per cycle			
15.	Average duration of treatment in days or cycles per year			
16.	Total product cost per patient per year			
17.	Additional cost per patient per year			

18.	Total annual cost per patient			
Section 2: Rationale for Application and Comparators				
19.	Rationale for listing application			
20.	Details on rationale for listing application			
21.	Existing product(s) for same indication			
Section 3: Supporting Clinical Evidence (Safety, Quality and Clinical Use)				
22.	Certificates of analysis, GMP certifications and/or Certificate of Origin/ health declarations			
23.	Information on adverse events, contraindications, precautions, and potential interactions with other medications/ post-marketing surveillance data if available.			
24.	Summary of relevant clinical studies/ journal articles/ pharmacopeia, monograph or classical reference/ treatment guidelines			
Others				
25.	T&CM Product Price Declaration Form (Appendix 5)			
26.	Cost Comparison (Appendix 6)			
27.	Sample of product (one unit only with packaging/ box) if requested			
28.	Product information leaflet			

Filled in by: *Please state applicant's name, designation, organisation, email address and contact no.*

Date:

Note:

- Incomplete documents will not be processed.
- Each application should only pertain to one product.
- All documents must be submitted in softcopy, with hardcopies provided upon request.

FOR SECRETARIAT USE	
Dossier receipt date	
Dossier complete date	
Reference no.	
Checked by	
Comments	

APPENDIX 4(ii): DOSSIER T1 (C) FORM

Instructions

- Applicant should provide detailed information about the T&CM product for traditional Malay medicine (TMM) practices as required in the form below.
- The information should be obtained from official reliable sources for example pharmacopeia, monograph or classic references.
- All information, references or supporting evidence submitted, if it is not written *in Bahasa Malaysia* or English, the applicant shall submit a copy in its original language and a translated copy in either *Bahasa Malaysia* or English.
- All applications must attach their latest packaging insert and label, where relevant.
- Sample of product should be provided upon request by the Secretariat.

Section 1: Product Information		
A. Particulars		
1.	Generic name	*Provide full generic name of the product according to the classic references (if relevant)*
2.	Active ingredient and strength	*Provide all active ingredients of the product and strength for each ingredient*
3.	Type of formulation	*State the type of formulation (e.g. single herbs, formula herbs, mixed ingredient)*
4.	Dosage form	*State the dosage form (e.g. granules, tablets, capsule or oil)*
B. Clinical and Pharmacological Information		
5.	Proposed indication(s) for the MOH T&CM Formulary	*State the proposed indication(s) to be listed in the MOH T&CM Formulary. Provide references.*
6.	Propose course of treatment (duration) and repeat if any	*State the recommended duration of treatment and/or treatment cycle. Provide references.*
7.	Warning/ Precaution	*State all warnings and precautions. Provide references.*
8.	Contraindication	*State all contraindications. Provide references.*
9.	Storage condition	*State the storage information. Provide references.*
10.	Adverse reactions	*State all adverse reactions. Provide references.*
C. Marketed Product and Related Treatment Costs		
11.	Details of Marketed Product(s)	*(to name at least one (1) example of marketed product in Malaysia)* Product Name: *State the product's trade name* Active Ingredients: *State all the active ingredients and strength of each active ingredient* Registration Holder: *State company's name and address* Manufacturer: *State company's name and address*

		Registration No.: *State DCA Registration no. / Notification no. of the product, and provide relevant Approval Letter/ certificate. Not compulsory for product exempted from registration* DCA Approved Indication (if applicable)*: State the DCA approved indication for DCA registered product* Declaration of products containing animal sources (if applicable): *State the origins of the ingredients used in preparing the product (if relevant), including the scientific name and common name of the animal source, part used, and country of origin.*
12.	Packaging size and price per item (RM)	*State the nett price of the product per packaging to MOH institutions, inclusive of all fees. Submit details as required in Product Price Declaration Form (**Appendix 5**).*
13.	Price per dosage unit (RM): (a)	*State the nett price, inclusive of all fees.*
14.	Number of dosage units administered per day or per cycle (b)	*State the number (or average number) of dosage units administered per day or per cycle.*
15.	Average duration of treatment in days or cycles per year (c)	*State the average/ maximum duration of treatment in days or number of cycles per year. If the treatment is continuous for 1 year, use 365 days.*
16.	Total product cost per patient per year (d) d= a x b x c	*This can be calculated by multiplying a, b and c*
17.	Additional cost per patient per year (e)	*List all potential additional costs, if relevant. Calculate potential additional costs per patient per year. This may include cost of drug monitoring and administration, cost of additional equipment required, costs to control adverse effects etc.*
18.	Total annual cost per patient (f)	*f = (d + e)*

A cost comparison between new proposed T&CM product and existing products that is used for the same indication should be submitted by using **Appendix 6**.

Section 2: Rationale for Application and Comparators	
C. Rational for listing application:	
Tick (/) the main reason(s) to list the product:	
	Insufficiently treated condition
	Has therapeutic advantage over an existing product(s)

	A cheaper alternative to an existing product(s)
	Complementary to existing therapies
	Improve compliance
	Others (please specify below)
B. Details on rationale of the application:	
Explain in detail the rationale/ justifications to list this product or amendment for the existing product. E.g. the advantages and differences of the proposed product over the available therapies in the MOH T&CM Formulary.	
C. Existing product(s) for the same/ similar indications in MOH T&CM Formulary	
List all the existing product(s) in MOH T&CM Formulary with the same/similar indication(s). Provide product names, strengths and dosage forms.	

Section 3: Supporting Evidence (Safety, Quality and Clinical Use)	
Data	**Description**
Quality	Supporting documentation shall include certificates of analysis, such as microbial contamination tests, heavy metal contamination tests, and biomarker analyses (where applicable), as well as Good Manufacturing Practice (GMP) certification and other relevant quality-related documents. For imported T&CM products, a Certificate of Origin shall be provided. Products containing animal-derived ingredients shall also be accompanied by a health declaration or Transmissible Spongiform Encephalopathies (TSE) risk evaluation certificate, where applicable.
Safety	Information on adverse events, contraindications, precautions, and potential interactions with medicines, herbs, food, or disease states shall be provided. Relevant preclinical or clinical safety studies should be included, together with post-marketing surveillance data, where available.
Clinical Use	Evidence supporting clinical use shall include relevant traditional knowledge and ethnopharmacological evidence from reliable sources, such as pharmacopeia, monographs, or classical references. In addition, a summary of relevant clinical studies conducted on the T&CM product is encouraged, including randomised controlled trials, observational studies, systematic reviews, and meta-analyses.

The applicant should include supporting documents that provide evidence of the quality, safety and therapeutic use of the product for listing purposes.

APPENDIX 5
PRODUCT PRICE DECLARATION FORM

No.	Pricing Details	For Applicant	For Secretariat Use
1.	Product Name (Trade Name)		
2.	Generic Name and Active Ingredient (including strength for each ingredient)		
3.	Registration Holder		
4.	Manufacturer & Country of Origin		
5.	Packaging Size		
6.	Nett Price Per Packaging (RM) (Inclusive of e-Perolehan Fee)		
7.	Nett Price Per Unit (RM) (Inclusive of e-Perolehan Fee)		
8.	Public Wholesale Price per unit **(**RM) in two (2) countries		
9.	Public Wholesale Price per unit (RM) in Country of Origin		

Authorised Signatory

I, the undersigned, hereby declare that the pricing information provided in this form is true, accurate, and complete to the best of my knowledge and professional responsibility. I acknowledge that this information will be used by the Ministry of Health Malaysia for evaluation and cost comparison purposes under the MOH T&CM Formulary.

Signature:
Name:
Designation:
Contact no.:
Email Address:
Company's Stamp:
Date:

Notes:

- This form shall be completed and signed by the supplier or company and submitted by the MOH applicant as part of the dossier.
- Submission of this form does not constitute any procurement commitment by the Ministry of Health Malaysia.

APPENDIX 6
COST COMPARISON

This appendix is used to compare the annual cost per patient of a proposed new T&CM product with an existing product in the MOH T&CM Formulary for the same or similar indication(s), to support cost assessment during the evaluation process.

Details	**New T&CM Product (Product Name:……)**	**Comparator (Product Name:……)**
Price per dosage unit (RM): (a)	RM	RM
Number of dosage units administered per day or per cycle (b)		
Average duration of treatment in days or cycles per year (c)		
Total product cost per patient per year (d) d= a x b x c	RM	RM
Additional cost per patient per year (e)	RM	RM
Total annual cost per patient (f) f= d+e	RM (x)	RM (y)
Difference annual cost per patient x-y	RM	

Notes:

- Prices shall reflect net prices to MOH, inclusive of applicable fees.
- Additional costs may include monitoring, consumables, administration, or management of adverse effects, where relevant.
- Where more than one comparator is applicable, additional tables may be submitted.

APPENDIX 7
T&CM PRODUCT DE-LISTING SUBMISSION FORM

Proposal to delist T&CM product/ indication from the MOH T&CM Formulary *Please tick (/)* Product ( ) Specific Indication only ( )		
A. Product Particulars		
1.	Generic Name	*Provide full generic name as listed in the MOH T&CM Formulary*
2	Dosage Form	*Provide dosage form as listed in the MOH T&CM Formulary*
3	Indication(s) to be deleted	*Specify the indication(s) to be removed. If proposing to de-list the entire product, state "All approved indications"*
4	Other relevant information	*If any*
B. Rationale for Deletion *Tick (/) the main reason(s) to de-list the product from the MOH T&CM Formulary*		
	Withdrawal from the global or local market	
	No or low usage of the product	
	Changes in policy or practice	
	Emergency safety concerns or adverse findings	
	Others (please specify):	
C. JUSTIFICATION		
Please provide a clear justification for the proposed de-listing and attach relevant supporting documents, where applicable (e.g. safety alerts, utilisation data, policy directives).		
D. Alternative Product(s) in the MOH T&CM Formulary		
Please list alternative product(s) available in the MOH T&CM Formulary for the same or similar indication(s), where applicable.		
E. Other Remarks (If Any)		

FOR SECRETARIAT USE	
Date Received	
Reference No.	
Checked by	
Comment	

APPENDIX 8
T&CM PRODUCT INFORMATION UPDATE REQUEST FORM

A. PRODUCT INFORMATION	
Generic name	*Provide full generic name as listed in the MOH T&CM Formulary*
Formulation / Dosage Form:	*Provide type of formulation/ dosage form as listed in the MOH T&CM Formulary*
Active Ingredients and Strength (if applicable):	*Provide list of active ingredients and strengths*

B. TYPE OF INFORMATION TO BE UPDATED *(Please tick (✓) where applicable)*			
	Formulation name		Herb-herb/ Herb-drug Interactions
	Dose and administration		Adverse Drug Reactions
	Contraindications		Precautions/ Warnings
	Others (please specify):		

C. DETAILS OF INFORMATION UPDATE

Current Information:
(As currently stated in the MOH T&CM Formulary)

Proposed Updated Information:
(Clearly state the revised information)

Reason / Justification for Update:
(e.g. new evidence, safety concern, regulatory update, clinical practice change)

D. SUPPORTING DOCUMENTS

(Please list and attach relevant references)

☐ DCA-approved product information leaflet
☐ Clinical guidelines
☐ Published literature
☐ Safety reports / alerts
☐ Others (please specify): _____

FOR SECRETARIAT USE	
Date Received	
Reference No.	
Checked by	
Comment	