MOH/S/FAR/113.24(GU)-e

MINISTRY OF HEALTH

GUIDELINES ON SUBMISSION OF DOSSIER FOR LISTING INTO THE MINISTRY OF HEALTH MEDICINES FORMULARY

THIRD EDITION

2024

PHARMACY PRACTICE & DEVELOPMENT DIVISION

PUBLISHED BY:
Pharmacy Practice & Development Division, Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor
Malaysia

MOH registration serial no.: MOH/S/FAR/113.24(GU)-e
Document registration no.: A-GU-12/3

Available at the following website(s):
https://www.pharmacy.gov.my/

This guideline shall be read in conjunction with the current laws and regulations together with other relevant legislations or guidelines, where applicable, but not limited to the ones listed in the references list.

ACKNOWLEDGEMENTS

The Pharmacy Practice & Development Division, Ministry of Health Malaysia would like to express gratitude to those directly or indirectly involved in preparing the Guidelines on Submission of Dossier for Listing into the Ministry of Health Medicines Formulary.

ADVISOR

Mdm. Norhaliza A Halim
Senior Director
Pharmaceutical Services, Ministry of Health

PHARMACY PRACTICE & DEVELOPMENT DIVISION, MINISTRY OF HEALTH

Mdm. Wan Noraimi Wan Ibrahim
Director

Dr. Nur Sufiza Ahmad
Deputy Director (Formulary Management)

SECRETARIAT (FORMULARY MANAGEMENT)

Dr. Rosliana Rosli
Senior Principal Assistant Director

Dr. Nur Liyana Zainal Bahrin
Senior Principal Assistant Director

Ms. Nabila Abdul Rahman
Senior Principal Assistant Director

Ms. Ng Sin Yee
Principal Assistant Director

DRUG EVALUATION & PHARMACOECONOMICS (FORMULARY MANAGEMENT)

Mdm. Haarathi Chandriah
Senior Principal Assistant Director

Mdm. Nazatul Syima Idrus
Senior Principal Assistant Director

Mdm. Nurulmaya Ahmad Sa'ad
Senior Principal Assistant Director

Ms. Coleen Choo Siew Bee
Senior Principal Assistant Director

Dr. Azmi Nor Mohd Farez Ahmat
Senior Principal Assistant Director

Mdm. Izzati Mohd Farok
Senior Principal Assistant Director

Ms. Yong Yee Vern
Senior Principal Assistant Director

Pharmaceutical Association of Malaysia (PhAMA), Malaysian Organisation of Pharmaceutical Industries (MOPI), Malaysian Association of Pharmaceutical Suppliers (MAPS), Malaysian Pharmacist Society (MPS), doctors, pharmacists and other organisations/individuals who had contributed their comments and suggestions in the development of this guideline.

ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reaction
APPL	Approved Product Purchase List
BIA	Budget Impact Analysis
CDCR	Control of Drugs and Cosmetics Regulations
CEA	Cost Effectiveness Analysis
CPG	Clinical Practice Guidelines
DCA	Drug Control Authority
DEC	Dossier Evaluation Committee
DTC	Drug and Therapeutics Committee
DWC	Drug Working Committee
FDC	Fixed Dose Combination
LOA	Letter of Acceptance
LOI	Letter of Intent
LOR	Letter of Rejection
LP	Local Purchase
MDA	Medical Device Authority
MOH	Ministry of Health
MOHMF	Ministry of Health Medicine Formulary
MyIPO	Intellectual Property Corporation of Malaysia
N/A	Not Applicable
PRH	Product Registration Holder
PPDD	Pharmacy Practice and Development Division
PSP	Pharmaceutical Services Programme
SSM	Companies Commission of Malaysia (*Suruhanjaya Syarikat Malaysia*)
WHO	World Health Organisation

GLOSSARY

Active Ingredient	Any component of a drug product intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals (1)
Ayurvedic medicines	A medical system from India that has been used for thousands of years. The goal is to cleanse the body and to restore balance to the body, mind, and spirit. It uses diet, herbal medicines, exercise, meditation, breathing, physical therapy, and other methods (2)
Biosimilar	A new biological medicinal* product developed to be similar in terms of quality, safety, and efficacy to an already registered (approved), well-established, biologic medicinal product (reference product**) (3) ** Biologic/ Biological product: Refers to a product whose active substance is made by or derived from a living organism (plant, human, animal or microorganism) and may be produced by biotechnology methods and other cutting-edge technologies. This product imitates natural biological substances* in our bodies such as hormones, enzymes or antibodies* (3) ***Reference product: A medicinal product already approved / registered in Malaysia on the basis of a complete dossier (quality, safety and efficacy) chosen as a reference product by the biosimilar manufacturer. The chosen reference medicinal product should be used throughout the development program for quality, safety and efficacy studies during the development of a biosimilar product* (3)
Category of prescriber / Prescriber category	Prescriber category authorised to initiate the prescription for the medicine (4)
Cosmetics	Any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance or correcting body odours, protecting them or keeping them in good condition (5)
Complementary medicine	The terms "complementary medicine" and "alternative medicine" refer to a broad set of health care practices that are not part of that country's own traditional or conventional medicine and are not fully integrated into the dominant health care system (6)
Dietary supplement	A product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a. a vitamin; b. a mineral; c. an herb or other botanical; d. an amino acid; e. a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or f. a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (a) to (e) (7)

Dosage form	Dosage form is the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product. This includes such factors as: i. The physical appearance of the drug product; ii. The physical form of the drug product prior to dispensing to the patient; iii. The way the product is administered; and iv. The design features that affect frequency of dosing (8)
Drug	Includes any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally, for a medicinal purpose (9)
Fixed dose combination (FDC)	A finished pharmaceutical product that contains two or more active ingredients in a single dosage form (10)
Generic medicine	Medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use (11)
Health supplements	Any product that is used to supplement* a diet and to maintain, enhance and improve the health function of human body (3) **Supplement: Any product used to supplement a diet and to maintain, enhance and improve the health function of human body. It is presented in small unit dosage forms (to be administered) such as capsules, tablets, powder, liquids and shall not include any sterile preparations (i.e., injectable, eye drops) (3)*
Herbal remedy	Any drug consisting of a substance, or a mixture of substances produced by drying, crushing, or comminuting, but without subjecting to any other process, a natural substance or substances of plant, animal or mineral origin, or any part of such substance or substances (5)
Homeopathic medicines	Any pharmaceutical dosage form used in the homeopathic therapeutic system in which diseases are treated by the use of minute amount of such substances which are capable of producing in healthy person symptoms similar to those of the disease being treated (5)
Innovator medicine	The product that was first authorized worldwide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization (12)
Medicine	Any dosage form containing a substance approved for the prevention and treatment of disease (13)
Medical device	Any product used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excludes drugs (14)
Medicinal purpose	The treatment of human ailments (15)
Multisource product	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable (10)
New chemical entity	An active ingredient that contains no active moiety that has been previously listed in the MOHMF
Patent	A patent is an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem (16)
Peer economic status countries	Countries with similar economic status as Malaysia based on the classification by World Bank (17)

Product	A drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose; or a drug to be used as an ingredient of a preparation for a medicinal purpose (5)
Product registration holder	A locally incorporated company, corporate or legal entity, with permanent address and registered with the Companies Commission of Malaysia (SSM) (with business scope related to health/ pharmaceutical product) (3)
Public wholesale price	Procurement price in the Public/Government entity (Example: MOH, MOE, MOD & etc.)
Strength	The amount of drug substance contained in, delivered, or deliverable from a drug product, which includes: i. The total quantity of drug substance in mass or units of activity in a dosage unit or container closure (Example: weight/unit dose, weight/volume or weight/weight in a container closure, or units/volume or units/weight in a container closure) ii. The concentration of the drug substance in mass or units of activity per unit volume or mass (Example: weight/weight, weight/volume, or units/volume) (8)
Traditional medicine	Any product used in the practice of indigenous medicine, in which the drug consists solely of one or more naturally occurring substance of a plant, animal or mineral, of parts thereof, in the unextracted or crude extract form, and a homeopathic medicine (5)
Therapeutic claim	A claim that is not documented in established pharmacopoeia or monographs, or a claim which is not the traditional use of the ingredient. It may include corroboration and verification of traditional use to relieve a symptom or help to treat a disease, disorder or medical condition, and it must be substantiated by scientific evidence (3)

TABLE OF CONTENTS

INTRODUCTION

The Ministry of Health Medicines Formulary (MOHMF) serves as a reference for medicines to be used in health institutions in the Ministry of Health (MOH). All medicines listed in the formulary are approved by the MOHMF Panel[1] (referred to as the Panel henceforth), chaired by the Director General of Health.

MOHMF is an administrative approach to encourage the rational and quality use of medicines in Malaysian MOH facilities. It consists of clinically relevant and cost-effective medicines that are considered essential for managing common disease affecting the majority of patients. The online version of the MOHMF is accessible on the Pharmaceutical Services Programme (PSP) official website: *www.pharmacy.gov.my*.

This guideline acts as a guide for applicants from pharmaceutical industries and MOH facilities intending to submit a dossier for listing of new medicines/ indications or amend information in the MOHMF. The requirements in this guideline are designed to promote uniformity of submissions and minimise variability in the quality of the dossiers submitted. The Pharmacy Practice and Development Division (PPDD) acts as the Secretariat to the MOHMF Panel and is responsible for processing the dossier submissions (referred to as the Secretariat henceforth).

This guideline provides practical information on how to prepare a complete dossier. A complete dossier with accurate information is essential as it helps to expedite the review process of submission. It will also facilitate a comprehensive assessment of the proposed medicine by the reviewers and consequently, the Panel's decision-making process. Nevertheless, a complete application does not guarantee the listing of medicine into the MOHMF.

Scope of this Guideline

The scope of the guideline includes procedures to propose listing of new medicines/ indications for medicinal purpose or amend information in the MOHMF. For listing of medicines into the MOH facilities' formulary, facility may refer to *"Tatacara Pengendalian Mesyuarat Jawatankuasa Ubat dan Terapeutik di Fasiliti Kementerian Kesihatan Malaysia Edisi-2, 2024".*

This guideline does not cover the following categories:

1. Cosmetics
2. Health supplements for general well-being (3)
    i. Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, and other bioactive substances
    ii. Substances derived from *natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolite
    iii. Synthetic sources of ingredients mentioned in (i) and (ii) may only be used where the safety of these has been proven.
3. Traditional and complementary medicines including homeopathic medicines, ayurvedic medicines and herbal remedy.
4. Medicines classified as medical devices which registered under the Medical Device Authority (MDA) Malaysia

[1] The MOHMF Panel is confidential.

TYPES OF DOSSIER & FEES

1. Dossier for listing a new medicine, indication, dosage form or strength into MOHMF should be submitted by the product registration holder (PRH) or a locally registered company authorised in writing by the PRH. MOH Drug Working Committee (DWC) & other programme/ division in MOH are allowed to submit these types of dossiers for multisource medicines only.

2. The PRH (or the locally appointed company), DWC & other programme/ division in MOH will be responsible for all matters related to their dossier submission, including transactions and correspondence with the Secretariat.

3. Dossier for changing prescriber category and delisting of medicine or indication should be submitted by consultants/ specialists/ medical officers/ dentists/ pharmacists working in MOH facilities or chairman of DWC.

4. Types of dossier submission, applicant and their corresponding processing fees are as below:

Table 1: Type of dossiers, applicants and fees

TYPE OF DOSSIER	DETAILS	APPLICANT	FEES (per dossier)
D1	**To list:** a. **new medicine*** b. **new indication*** for existing medicines	• PRH • DWC** • Programme/ Division, MOH**	a. RM5,000.00 b. RM3,000.00
D2	**To add dosage form/ strength**		RM2,000.00
D3	**To change category of prescriber**	• MOH facilities	N/A
D4	**To delist approved medicine/ indication**	• MOH facilities	N/A

Note:
* The number of medicine or indication to be proposed is limited to ONE medicine or indication per dossier
** Submission of dossiers for multisource medicines only. Processing fees are waived.

5. Payment has to be made within 15 working days after the date of screening approval (completeness of documents and completion of BIA screening). Failure to make payment within stipulated time shall result in rejection of the application.

6. An application shall only be forwarded for evaluation once payment has been approved.

7. The same processing fees apply for both initial submission and resubmission. The processing fees charged upon submission and resubmission of dossiers are **NON-REFUNDABLE**. Official receipt will be issued within **five (5) working days**.

8. The fees, in the form of **bank draft/ money order/ postal order** should be made payable to **'KETUA SETIAUSAHA, KEMENTERIAN KESIHATAN MALAYSIA'**.

SECTION A: LISTING PROCESS

(Applicable for D1, D2 & D3 dossier submission)

Applicant may submit a complete dossier of D1, D2 and D3 for consideration anytime of the year.

1. INTENTION TO SUBMIT

1.1. LETTER OF INTENT (LOI)

ELIGIBILITY CRITERIA

1.1.1. Submission of dossier D1, D2 and D3 must be initiated with a letter of intent (LOI) using the **company/MOH facility official letterhead.**

1.1.2. For D1 and D2 dossier submissions, the medicine intended for listing into the MOHMF must **fulfill the following eligibility criteria** at the time of submitting the LOI:

Table 2: Eligibility criteria for dossier submission for listing into the MOHMF

ELIGIBILITY CRITERIA	DOSSIER	
	D1	D2
1. New chemical entity (NCE) must be registered with the Malaysia Drug Control Authority (DCA) for at least 12 months *(**Note**: Not applicable for listing of new indication)*	/	-
2. Indication must be approved by the Malaysia DCA	/	/
3. The medicine (and its indication(s)) applied for listing is listed in the reimbursement list/ national formulary in at least two countries	/	/
4. Medicine must have been used at least in the recent 6 months post DCA registration in Malaysia *(**Note**: Not applicable for D1 dossier: add indication)*	/	/
5. Medicine must have therapeutic and/or safety advantages	/	/

1.1.3. For D3 dossier submission, justification for change in prescriber category must be provided upon the submission of LOI

LISTING OF NEW CHEMICAL ENTITY

1.1.4. A new chemical entity (NCE) is a new product containing an active ingredient that has not been listed in the MOHMF.

LISTING OF FIXED DOSE COMBINATION (FDC)

1.1.5. Each single active ingredient must be listed first before the FDC can be considered for listing into the MOHMF.

1.1.6. Type of dossier to be submitted depends on the listing status of each active ingredient:

a. D1 Dossier: If one or more of the active ingredients is not listed as single agent in the MOHMF
b. D2 Dossier: If all the single active ingredient(s) are listed in the MOHMF and the proposed indication(s) of the FDC product is similar to the indication(s) listed for each of its active ingredient.

1.1.7. Exemption can be considered for active ingredients that do not require dose titration or do not exist as a single commercial product (Refer example 1.1.8 c).

1.1.8. Examples:

a. Drug A is listed in the MOHMF, while drug B is not – the listing of FDC (AB) should be proposed through submission of Dossier D1.

b. Drug A and drug B – both are already listed in the MOHMF - the listing of FDC (AB) should be proposed through submission of Dossier D2 (add dosage form).

c. Drug A and drug B are not listed in the MOHMF and do not exist as a single commercial product - the listing of FDC (AB) should be proposed through submission of Dossier D1.

SUPPORTING DOCUMENT(S) FOR LOI

1.1.9. The complete LOI must be submitted along with the following **supporting documents:**

Table 3: Supporting documents for letter of intent (LOI)

DOSSIER	LOI	DOCUMENT(S)
D1	**Appendix 1A**	**Submission by PRH:** • LOI signed by a ***corporate/market access manager/ appointed officer** of the company • **URL/snapshot/document of national reimbursement/ formulary in at least two countries** *(containing information on generic name, indication and approval)* • **Sales report/ evidence of usage for the recent six months** *(Example: summary of sales which contains information on date for first sale, quantity for public and private sectors without stating the name of facilities involved).* • **Executive summary of updated Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER)** *(Local safety report is preferred)* • **Summary and citation (Vancouver style) of the comparative effectiveness and/or safety studies** *(Head-to-head studies are highly preferred)* **Submission by DWC/Other Programmes/Division in MOH** *(multisource medicines)*: • LOI signed by **Chairperson** of the DWC *(Contact person shall be the Secretary of the DWC)* / Head of Programme/Division • **Drug utilisation data** for the **recent six months** *(Example: procurement data for facilities/MOH)*
D2		
D3	**Appendix 1B**	**Submission by MOH facilities:** • LOI signed by ***consultants/ specialists/ medical officers/ dentists/ pharmacists working in MOH facilities or chairperson of DWC** • **Relevant supporting documents** which support the rationale of application *(Example: summary of clinical evidence)*

***Note**: *This person will also act as the contact person for this dossier. Details for contact person shall be provided if different from signee.*

1.1.10. In addition to above requirements (for submission by PRH), if the product has been listed into the MOHMF:

a. the company has to issue a six-month notice before any product withdrawal from the market.
b. the company has to provide one year utilisation data post-listing.

1.1.11. A scanned copy of signed LOI (PDF format) and the supporting documents must be **emailed** to **cpfor@moh.gov.my**.

1.2. LETTER OF ACCEPTANCE (LOA)

1.2.1. Letter of Acceptance (LOA) will be issued to the applicant within **five (5) working days** of receiving the LOI if the application meets the eligibility criteria. A **complete dossier** of the proposed medicine with all the supporting documents, including a **copy of the LOA**, has to be submitted within **six (6) months** from the date of LOA.

1.2.2. The LOA will be considered **VOID** if the dossier is **not submitted** within the stipulated time and a new LOI has to be submitted.

1.3. LETTER OF REJECTION (LOR)

1.3.1. The LOI will be rejected under these following circumstances:

a. the medicine does not meet the eligibility criteria at the time of submitting the LOI.
b. proposal is for listing a product belonging to the following categories:
   - Cosmetics
   - Health supplements for general well-being
   - Traditional medicines including:
     - Homeopathic medicines
     - Ayurvedic medicines
     - Herbal remedy
   - Dietary supplements; *Example: Spirulina, Chlorella, Royal Jelly, Bee Pollen, Aloe Vera juice, Noni juice etc.*
   - Drugs classified as medical devices registered under the Medical Device Authority (MDA) Malaysia

1.3.2. LOR will be issued to the applicant within **five (5) working days** of receiving the LOI.

NOTE: The PRH must notify the Secretariat of any change in correspondence details, including the name, address, contact person, telephone number, fax number and email address.

2. PRE-SUBMISSION MEETING

2.1. Applicant may request **ONE** pre-submission meeting either:

i. **Early Pre-Submission Meeting** - before submission of LOI

ii. **Standard Pre-Submission Meeting** (**within 6 months** after the issuance of LOA)

2.2. The meeting is intended to offer an opportunity for applicants to seek clarification on matters pertaining to submission requirements only.

2.3. The meeting will be scheduled for a maximum of **one hour** and limited to **one dossier submission** per session.

2.4. The applicant is required to email the MOHMF Pre-submission Meeting Request Form as in **Appendix 2** to cpfor@moh.gov.my at least **seven (7) days** before the proposed meeting date (subject to availability of the Secretariat). A maximum of **three (3)** representatives from the company are allowed in each session.

2.5. The meeting shall be either via video conference or in person. The decision to accept the request, including the mode of meeting, will be made by the Secretariat on a case-by-case basis.

3. PREPARATION OF DOSSIER

PART A: DOSSIER FORMS

3.1. Information on product details must be in line with the information approved by the DCA and obtained from official reliable sources (*Example: medicine monograph or product information leaflet*).

3.2. For D1 and D2 dossier submissions:

3.2.1. It is highly recommended that, the applicant submits all relevant strengths of the dosage form which fit the dosage recommendation for the indication proposed for listing.
Example: Drug A is available in 5mg, 10mg and 15mg tablets. The recommended dose is between 5 - 15mg. Therefore, applicants should submit all three strengths for listing to facilitate dose adjustment especially if the tablet cannot be split and can encourage patient compliance.

3.2.2. Overview of the disease, current management and the patient population that the product is targeted at, including epidemiological data (global and/or local), should be provided.

3.3. For dossiers D1, D2 and D3, rationale/justification for dossier submission must be submitted including proposed place of therapy and specific patient population that will benefit from the medicine.

3.4. Applicant should list all the existing medicine(s) in MOHMF with the same/similar indication(s), same therapeutic class and other alternatives.

3.5. When preparing a dossier, the relevant forms, checklists and documents must be used:

Table 4: Forms, checklists and documents for dossier submission

NO.	DOCUMENTS	APPENDICES FOR EACH TYPE OF DOSSIER		
		D1	D2	D3
1	Checklists for dossiers	3(a)	4(a)	5(a)
2	Dossier Forms*	3(b)	4(b)	5(b)
3	Medicine Price Declaration Form*	6		
4	Cost Comparison and Financial Implication*	-	7	
5	Applicant Statement of Declaration	8(a)		8(b)

***Note**: *The guided instructions for dossiers detailing the expected contents are described in the template forms and should be complied.*

3.6. <u>Medicines price declaration:</u>

3.6.1. For submission by PRH, the price quoted in the Medicine Price Declaration Form is valid and will be monitored for two (2) years from the date of listing of medicine(s) in the MOHMF.

3.6.2. Price per unit quoted in this document shall be: Net Price (inclusive of agents' commission). Purchase price by MOH health facility after the listing in MOHMF **MUST NOT** exceed the price quoted.

NOTE: Panel has the right to review the listing of a medicine if PRH failed to comply with selling the medicine at the price quoted. MOH facilities should report to the Medicine Price Management Branch, Pharmacy Practice and Development Division, Ministry of Health via email: chu@moh.gov.my if the purchase price exceeds the quoted price.

PART B: SUPPORTING DOCUMENTS

3.7. The following supporting documents shall be submitted along with the dossier:

Table 5: Supporting documents for dossier submission

NO.	SUPPORTING DOCUMENTS	D1	D2	D3
1.	Copy of LOA	● #	● #	#
2.	DCA approved product information leaflet	● #	● #	-
3.	DCA indication certificate (upon request)	●	●	-
4.	Supporting Clinical Evidence (Effectiveness and Safety)			
a)	Summary of systematic search strategies for evidence	● #	● #	#
b)	Evidence tables for each research articles	● #	● #	#
c)	Supporting evidence for efficacy/effectiveness and safety *(softcopy)*	● #	● #	#
d)	Clinical trial/ study reports conducted in Malaysia (if any)	● #	● #	#
e)	Executive summary of Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)/Post Marketing Safety Report –Malaysia) *(softcopy)* (***Note**: For NCE only)*	●	-	-
5.	Supporting Economic Evidence			
a)	Economic studies/reports (if any)	● #	● #	-
b)	Evidence tables of economic studies	● #	● #	-
c)	Local economic evaluation (if any) i. report ii. live MS Excel format (*softcopy*)	● #	● #	-
d)	Budget impact analysis (**mandatory**) i. report ii. live MS Excel format *(softcopy)*	● #	-	-
6.	Others			
a)	List of references in Vancouver style	● #	● #	#
b)	Relevant treatment guidelines; if available (*softcopy*)	● #	● #	#

●*PRH # MOH facilities ;* ***Note**: Sample of medicine may be provided upon request.*

3.8. Evidence requirement differs based on the type of dossier submitted and the recommended number of journal articles to be submitted as below:

Table 6: Evidence requirement for dossier submission

TYPE OF DOSSIER	RECOMMENDED NUMBER OF JOURNAL ARTICLES / WRITTEN EVIDENCE	TYPE OF EVIDENCE
D1	5	Effectiveness and safety
	1	Budget impact analysis and/or economic evaluation
D2	3	Effectiveness and safety
	1	Economic evaluation
D3	1	Clinical evidence may be submitted if relevant.

3.9. The following sections will elaborate on the standard requirements and approach to furnish the **clinical** and **economic** evidence.

3.10. Clinical Evidence

3.10.1. The decision for listing of new medicines into the MOHMF is based on but not limited to the evaluation of the comparative clinical safety and effectiveness of the medicines.

3.10.2. Comprehensive, clear, latest and unbiased evidence most relevant to the indications and the targeted population should be provided.

3.10.3. Direct comparative effectiveness and safety of the proposed medicine to the current standard practice are highly preferred especially studies conducted in Malaysia.

3.10.4. Evidence from the highest available level of study design shall be submitted. All evidences submitted should be summarised in an evidence table (refer Appendix 9) and the level of evidence should be classified based on categories as shown below:

Table 7: Classification of evidence level

LEVEL OF EVIDENCE	DESCRIPTIONS
1++	High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 -	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2 -	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies (Example: case reports, case series)
4	Expert opinion

3.10.5. Systematic and comprehensive literature search on main search engines should be conducted. Details of systematic literature search including the following shall be reported:

a. search strategy
b. inclusion and exclusion criteria
c. the limits applied *(Example: language, year)*

3.10.6. Other relevant studies (published & unpublished) can be listed in full citation using Vancouver Style. Full text of these documents can be included in the electronic copy of the dossier.

3.10.7. Clinical progress reports on patients currently on the medicine including the summary of the relevant laboratory results/ indicators (if any) should be provided.

3.10.8. The applicant is responsible in providing any additional articles/ documents when requested by the Secretariat.

3.11. Economic Evidence

Economic evidence is one of the elements considered in decision making for formulary listing. There are two (2) categories of economic evidence required to be submitted:

3.11.1. Economic Evaluation

i. Applicant should attempt to submit full text articles of all relevant economic evaluations, which have been identified through a systematic literature search. A summary of each economic evaluation should be reported in an evidence table as shown in Appendix 10.

ii. The findings of economic evaluations conducted in other countries may not be directly applicable to the local setting due to major differences, for example, unit costs, health system and health care funding mechanism. Therefore, economic evaluations performed in the Malaysian health care setting are highly preferred. Thus, applicants are strongly encouraged to submit evidence from local economic evaluations.

iii. Conducting Local Pharmacoeconomic Evaluation

For the purpose of dossier submission, the types of economic evaluation accepted are cost-utility analysis (CUA) and cost-effectiveness analysis (CEA). CUA is strongly preferred. However, CEA may be acceptable in some circumstances. The economic evaluation should be conducted from the perspective of MOH Malaysia and can be supplemented with an analysis conducted from the societal perspective (if relevant/feasible).

A **full write up (report)** of the economic evaluation must be submitted together with **MS Excel live worksheet**. Complete disclosure of methodology including calculation and uncertainty should be provided in a live spreadsheet of MS Excel format. Calculations should be accessible to the user and allow replication of analysis. Abbreviations or legends used in the economic model must be clearly defined.

Local pharmacoeconomic research is not a compulsory requirement for submission of dossier D1. The applicant may refer to the Pharmacoeconomic Guideline for Malaysia on how to conduct pharmacoeconomic evaluation in the local setting which can be accessed online via www.pharmacy.gov.my.

3.11.2. Budget Impact Analysis (BIA)

i. For dossier D1 submission, a BIA conducted from the perspective of MOH Malaysia is a mandatory requirement. The information presented in BIA may assist the PPDD in providing recommendation to the Panel in making decision for listing a medicine into the MOHMF.

ii. The purpose of BIA is to estimate the financial consequences of adoption and diffusion of a new health-care intervention within a specific healthcare setting or system context given inevitable resource constraints. In particular, a BIA predicts how a change in the mix of drugs and other therapies used to treat a particular health condition will affect the trajectory of spending on that condition.

iii. A **full write-up (report) of BIA** must be submitted together with **MS Excel live worksheet**. Complete disclosure of methodology including calculation and uncertainty should be provided in a live spreadsheet of MS Excel format. Calculations should be accessible to the user and allow replication of analysis. Abbreviations or legends used in the BIA model must be clearly defined.

iv. Some points to be considered when performing BIA:
- Malaysian data (Example: prevalence of disease states, projected market shares from the MOH perspective or payer perspective) should be used, where possible. If local data is not available, other sources may be used if justification is provided, sources are adequately referenced, and assumptions stated.
- Five-year time horizon is required for all projections.
- Treatment mix must include all relevant comparators, formulary, or non-formulary medicines, which have same/similar indication as the proposed medicine.

v. For more information on principles of conducting a BIA, please refer to the latest Pharmacoeconomic Guideline for Malaysia which can be accessed online via www.pharmacy.gov.my.

4. SCREENING OF DOSSIER

4.1. After the full dossier has been submitted, the application shall undergo a screening process, which ensures that the submitted application is complete with the required data/ information.

4.2. Screening of dossier consists of:
i. screening for completeness of documents
ii. BIA screening (Dossier D1 only)

4.3. All dossiers must be accompanied by a dossier checklist. The dossier received will be screened for completeness of documents/ information based on the checklist of each dossier within seven (7) working days. A brief justification should be provided for any missing information or document.

4.4. The applicant will be contacted should there be any further queries or additional documents required. Applicant is required to provide feedback within stipulated time frame. If unable to do so, the applicant

should provide the justification and a new due date can be discussed with the Secretariat. If no satisfactory response after a maximum of three (3) reminders, the dossier will not be processed, and a new submission is required.

4.5. All submitted documents are deemed final upon submission of dossier unless there is new evidence/information after the dossier submission. The applicant can contact the Secretariat to submit the additional documents.

4.6. Any amendment by the applicant on the submitted dossier is NOT PERMITTED after 14 working days from the date of submission unless requested. A written request for amendment must be forwarded to the Secretariat and no verbal request will be entertained.

4.7. For Dossier D1, screening of the BIA shall be done at this stage and the first correspondence from the Secretariat is within 30 working days from BIA screening start date. BIA screening will be set at 90 working days subject to the complexity of the model or any arising issues. This timeline excludes stop clock for obtaining feedbacks from relevant stakeholders and applicant.

4.8. A maximum of three (3) correspondence is allowed during screening, after which if the BIA is not satisfactory, a post submission meeting may be offered to discuss the issues involved. However, the dossier will be considered incomplete and will be rejected by the Secretariat if it is still not satisfactory. The applicant may need to resubmit the dossier after cooling-off period of 3 months along with previous comments and changes in the model.

4.9. The requirements as per 4.7 and 4.8 above are also applicable for screening of CE model if a dossier is submitted with a local CE study.

4.10. The Secretariat may offer one post submission meeting each during screening to discuss issues arising from the BIA/CE model.

4.11. After screening is deemed satisfactory and approved for payment, the dossier shall be accepted for evaluation. Payment has to be made within 15 working days from the date of screening approval. The dossier will be rejected if payment is not made within this stipulated time. All information provided to the Secretariat will be treated as confidential.

5. EVALUATION OF DOSSIER

5.1. Upon confirmation of payment, the dossier shall be evaluated and completed within 90 working days. Evaluation of a dossier shall follow a queue system and the timeline shall commence after payment has been confirmed.

5.2. All dossiers will also be reviewed by MOH expert panels and relevant stakeholders.

5.3. The applicant will be contacted should there be any further queries or additional documents required. Applicant is required to provide feedback within stipulated time frame. If unable to do so, the applicant should provide the justification and a new due date can be discussed with the Secretariat. If no satisfactory response after a maximum of **three (3) reminders**, the dossier will not be processed, and a new submission is required.

5.4. The applicant is responsible to inform the Secretariat if any changes in DCA indication(s) occurred after dossier submission. Failure to do so, the Secretariat has the right to withhold or suspend the evaluation. In case a re-evaluation will be required, the applicant need to resubmit a new dossier with updated indication(s) and supporting documents after a cooling-off period of minimum 6 months.

5.5. The applicant will be contacted for post-submission meeting if there are issues, which are unable to be resolved through correspondence by email. Invitation for the meeting will be sent via email to the respective applicant.

6. PRESENTATION OF DOSSIER

6.1. The completed dossiers will be presented to the Dossier Evaluation Committee (DEC) within **30 days** before the scheduled MOHMF Panel Meeting.

6.2. MOHMF Panel Meeting is scheduled for 3 times a year as follows:

Table 8: MOHMF panel meeting schedule

MEETING NO.	MONTH
1	March
2	July
3	November

***Note**: Dates are subject to change.*

6.3. The Secretariat reserves the right to determine the number of dossiers to be presented in each meeting taking into consideration the time allocated for the meeting. The selection of dossiers to be presented is based on the sequence of evaluation completion. Applicants will be notified via email within **30 days** prior to the Panel Meeting if their dossier is scheduled for presentation.

6.4. The MOHMF Panel reserves the right to approve, reject, defer or make any decision related to the dossier. The outcome will be informed to the applicant via email **within three** (**3) working days** from the date of the Panel Meeting.

6.5. For dossiers that are not approved, a brief report with reasons of rejection will be provided together with the notification letter.

6.6. The applicant has to provide one year utilisation data post-listing for newly listed medicine in MOHMF which will be presented to the Panel.

7. NOTIFICATION TO THE APPLICANT

Applicant will be notified regarding the status of submission at the following stages, either by e-mail or official letter:

a. Acceptance of dossier
b. BIA screening start date (for Dossier D1)
c. Screening approval and payment instruction (applicable for submission by PRH).
   Dossier D1: BIA screening is completed
   Dossiers D2 & D3: A complete dossier is received
d. Official payment receipt and evaluation notification
e. Completion of dossier evaluation
f. Presentation of dossier in the Panel Meeting (within 30 days before Panel Meeting).
g. Decision of the Panel (within 3 working days from the date of Panel Meeting).

8. WITHDRAWAL OF DOSSIER

8.1. Withdrawal of dossier must be strongly justified and cooling-off period for resubmission will be imposed (refer ***Types of Dossier & Fees***). The processing fee is non-refundable for any withdrawal request.

8.2. A written request for withdrawal must be forwarded to the Secretariat. Any verbal request will not be entertained.

9. RESUBMISSION

9.1. Resubmission of dossier is defined as the submission of an application that has been presented in the Panel meeting but rejected or an application that was previously withdrawn by the applicant. A new LOI has to be submitted.

9.2. The decision made by the Panel is final and any dispute should be followed by a resubmission. Applicant is allowed to resubmit the same dossier for consideration provided that the **reasons for rejection are addressed appropriately** (Example: new evidence have emerged and/or significant cost reduction is proposed).

9.3. Resubmission of dossier should comply to cooling-off period as follows:

Table 9: Resubmission cooling period

Order of rejection/withdrawal	*Resubmission
1st rejection/withdrawal	3 months
2nd rejection/withdrawal	6 months
3rd rejection/withdrawal and subsequent	12 months

***Note**: * from the date of Panel Meeting/ withdrawal by applicant.*

9.4. Applicant is allowed to request for pre-submission meeting when there is plan to resubmit the dossier. Further clarification on the reason for rejection is allowed during the pre-submission meeting.

9.5. The workflows of listing medicine into the MOHMF are illustrated in **Figures 1** and **2**.

WORKFLOW OF LISTING MEDICINE INTO THE MOHMF (DOSSIER D1)

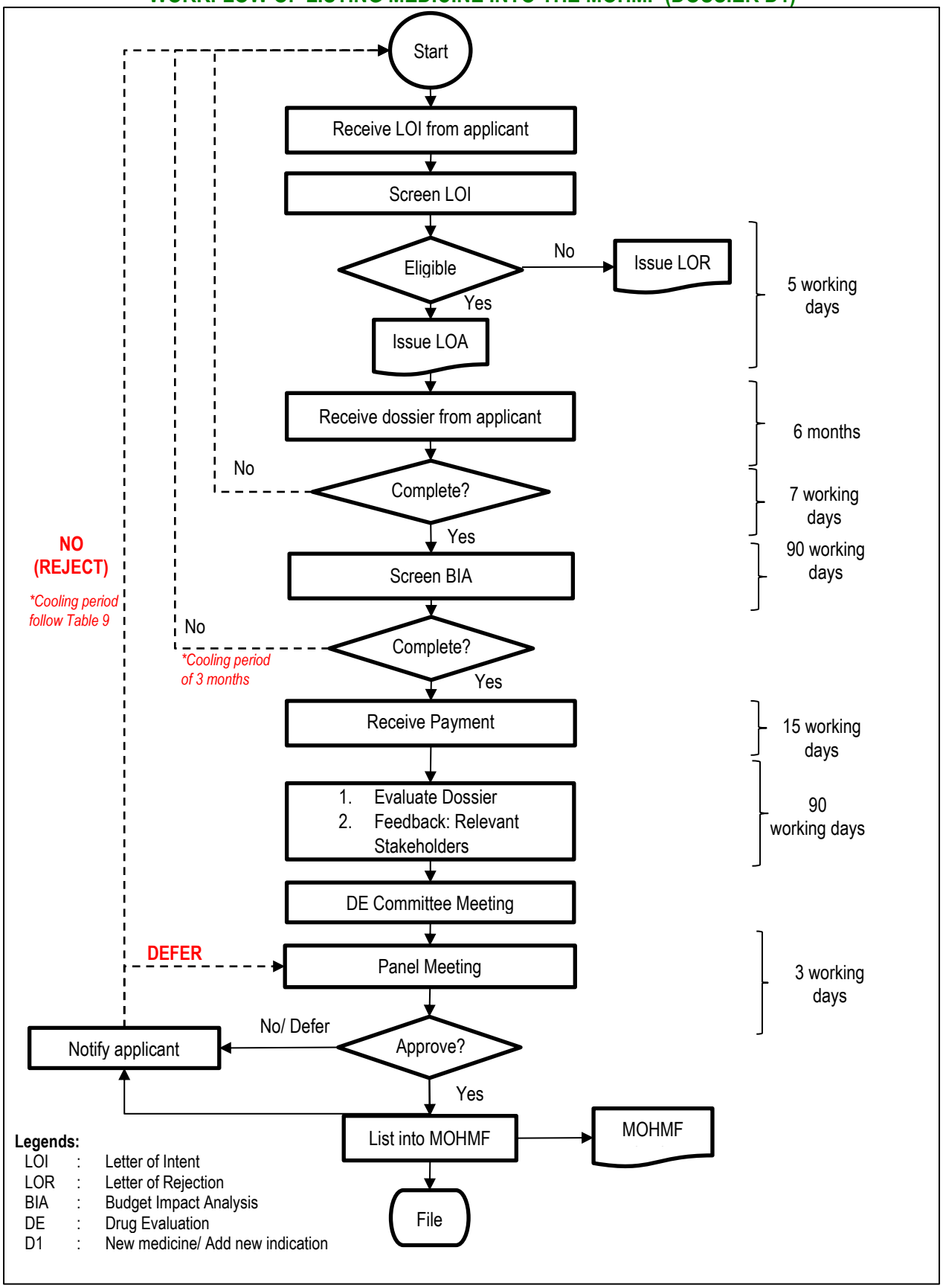

Figure 1: Workflow of listing medicine into the MOHMF (Dossier D1)

WORKFLOW OF LISTING MEDICINE INTO THE MOHMF (DOSSIERS D2 & D3)

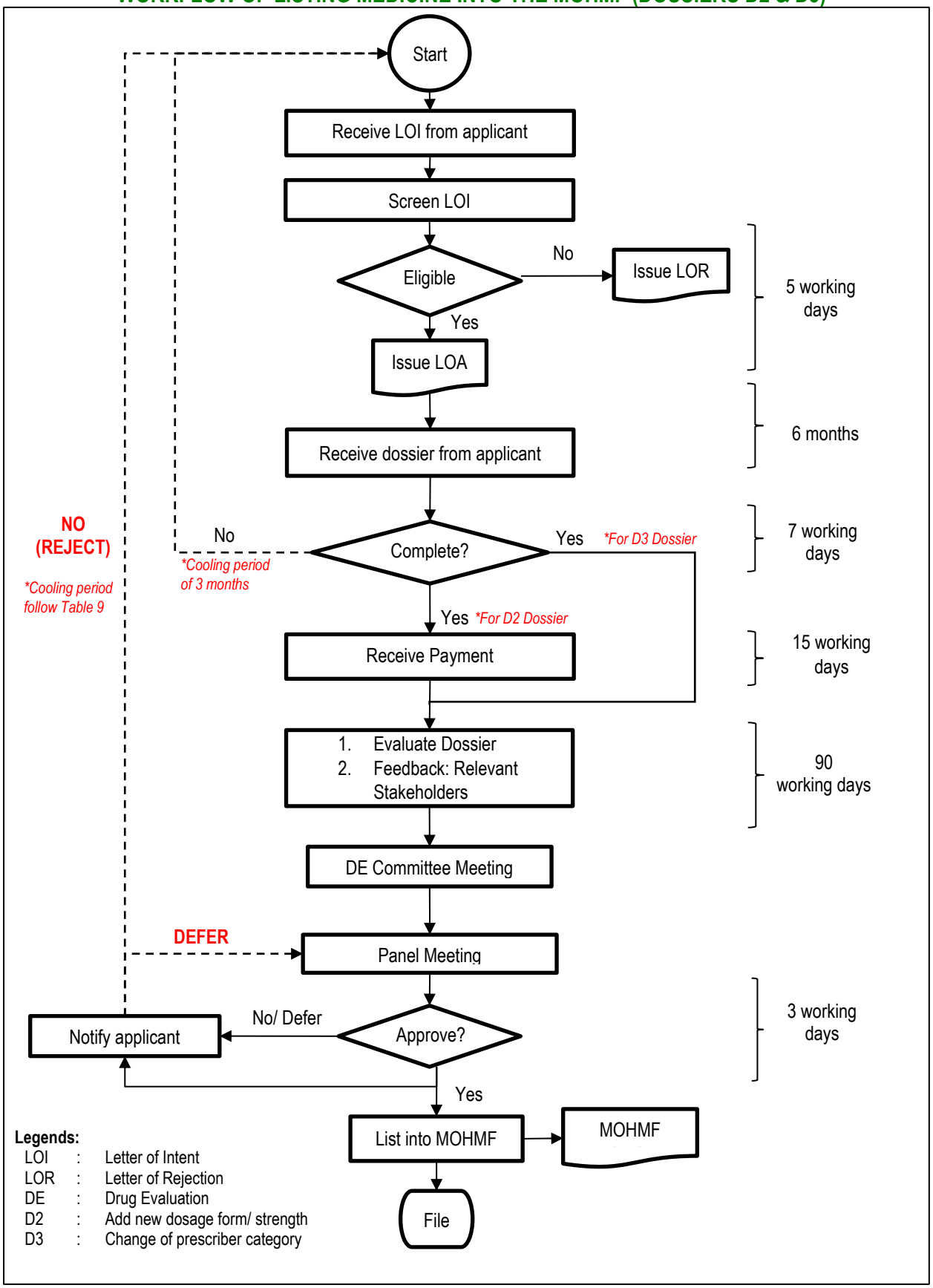

Figure 2: Workflow of listing medicine into the MOHMF (Dossier D2 & D3)

SECTION B: DELISTING PROCESS

Only applicants from MOH facilities may submit proposal to delist medicine/ indication listed in the MOHMF anytime of the year.

1. Proposal to delist any medicine / indication from the MOHMF can be done through Dossier D4 submission (**Appendix 11A**). There are several reasons for delisting of medicines including but not limited to:
   a. Withdrawal from global/local market
   b. No or low usage of the medicine
   c. Change in policy/ practice
   d. Safety issues

2. Proposal to delist medicines from MOHMF due to change in policy/practice or low/ no usage should be accompanied with current clinical evidence (example: CPG or related policy documents) and other relevant documents.

3. The dossier received will be screened and evaluated by the Secretariat. When necessary, the dossier will be reviewed by MOH expert panels and relevant stakeholders.

4. Dossier D4 will be presented in the MOHMF Panel meeting and the Panel reserves the right to approve, reject or defer any delisting proposal. The decision will be informed to the applicant via email/ official letter within **three (3) working days** from the date of the Panel Meeting.

5. Relisting of delisted medicine must be strongly justified and a written request for relisting must be forwarded to the Secretariat. Any verbal request will not be entertained. If dossier submission is deemed required, the process for listing of medicine into MOHMF will be decided on a case-by-case basis.

6. The workflow of delisting medicine from the MOHMF is illustrated in **Figure 3**.

WORKFLOW FOR DELISTING MEDICINE FROM THE MOHMF (DOSSIER D4)

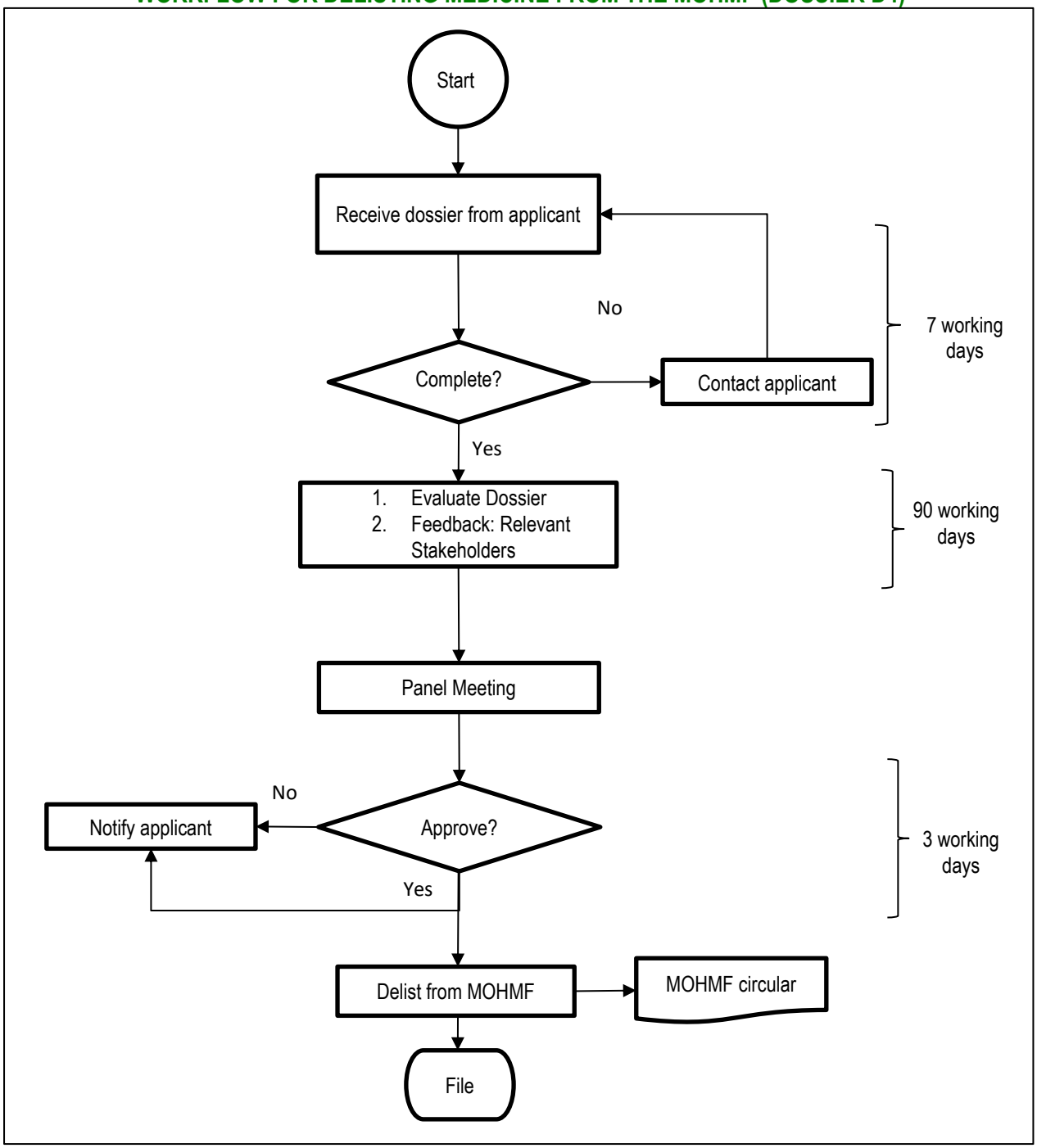

Figure 3: Workflow for delisting medicine from the MOHMF (Dossier D4)

SECTION C: PROPOSAL TO AMEND INFORMATION OF MEDICINE LISTED IN MOHMF

1. Any suggestion to update medicine information in listed in MOHMF can be submitted by filling out the Information Update Request Form (Appendix 12) and then submitted online at http://tinyurl.com/cadangfukkm.

2. Proposal can be submitted by any MOH healthcare personnel (including allied healthcare workers) and PRH. Information that can be proposed to be amended are such as generic name, drug interactions, indication, prescribing restriction (only by MOH personnel), adverse drug reactions (ADR), dose and contraindications.

3. Amendment on prescribing restriction can only be submitted by MOH facilities. The practice and use of drugs in MOH facilities can only be determined by healthcare professionals in MOH facilities without involving advice from pharmaceutical companies.

4. The proposal should be accompanied with supporting documents such as DCA approved product information leaflet, latest clinical guidelines and other relevant supporting documents.

5. Amendment on the indication is only applicable to existing indications listed in MOHMF.
   i. For innovator medicines, any additional indications will need to go through the MOHMF listing process via dossier D1 (add indication).
   ii. For multisource medicines, MOH facilities may propose additional indication via this form provided that the indication is registered with the DCA. However, this proposal will be reviewed on a case-by-case basis.

6. All proposals will be screened and reviewed by the Secretariat. The applicant will be contacted if further information is needed. If necessary, the proposal will be presented in the MOHMF Panel Meeting for decision.

7. The applicant will be notified regarding the results of this application via email.

8. The workflow of proposal to amend information of medicine listed into the MOHMF is illustrated in **Figure 4**.

WORKFLOW OF PROPOSAL TO AMEND INFORMATION OF MEDICINE LISTED IN MOHMF

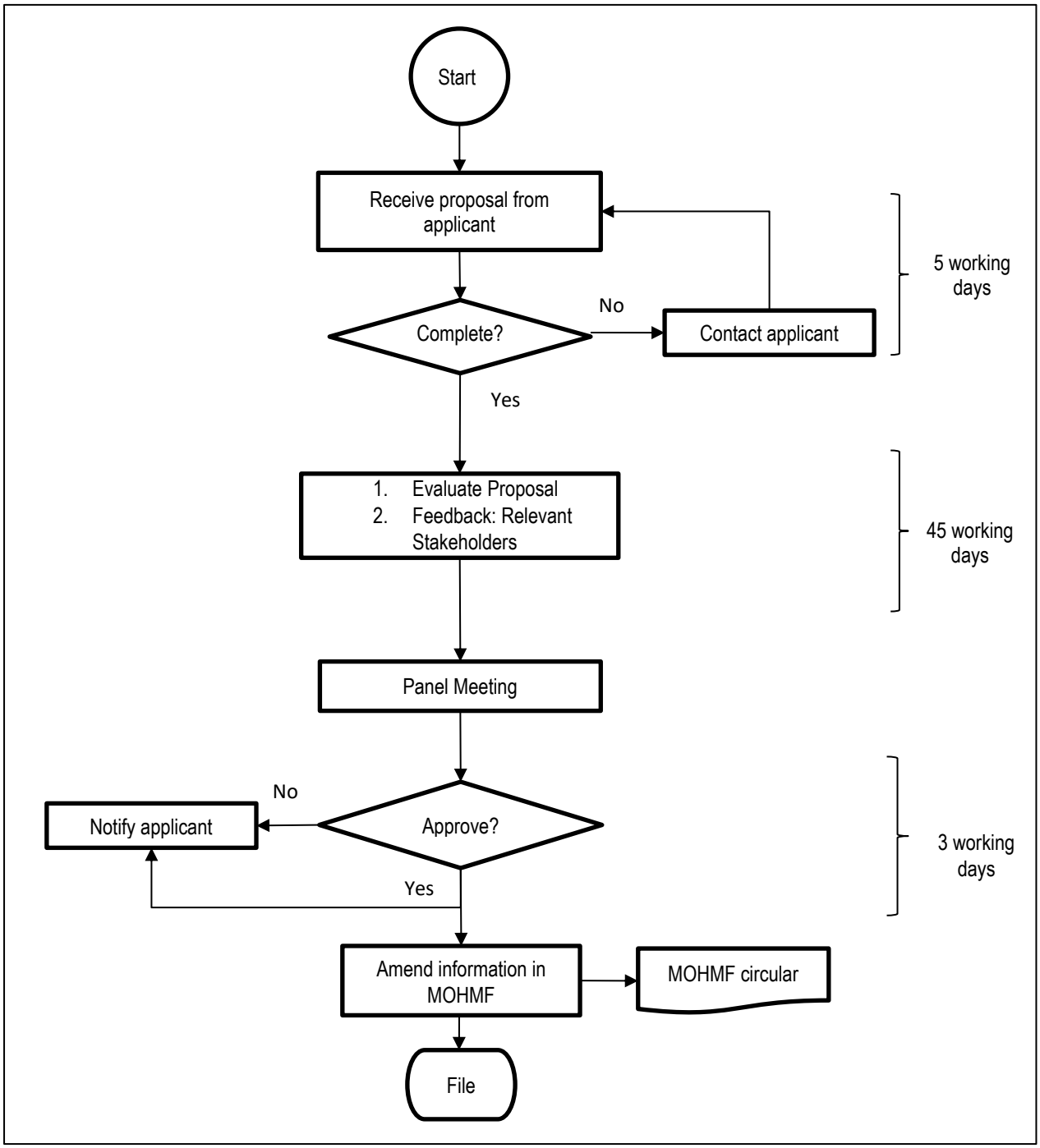

Figure 4: Workflow proposal to amend information of medicine listed in MOHMF

INSTRUCTIONS TO APPLICANT

1. FORMAT OF DOSSIER

To ensure uniformity of dossiers and to facilitate the evaluation process, a dossier should be prepared as follows:

Table 10: Format of dossier

PARTICULAR	FORMAT	NOTE(S)
Language	English	Documents that are in other foreign language should be translated to English.
Font	Arial	-
Font size	11	Font size should not be scripted or italicised except for scientific names and terms in a different language. **Bold** print may be used for headings.
Font colour	Black	Do not shade or highlight
Spacing	Single spacing	-
Paper size	A4	-
Page orientation	Portrait	-
Citation	Vancouver Style	-
Printing	Double sided, black and white	-
Filing of dossier	A4 size ring file	-
Divider	Coloured paper with index	Divider should be placed in front of each Section/ Appendix.

2. ARRANGEMENT OF DOSSIER

The **hardcopy** of the dossier should be arranged in order as below:

i. **COVER**
   File cover/front page with name of medicine, type of dossier, contact person (with email and phone number)

ii. **TABLE OF CONTENTS**

iii. **PART A: DOSSIER FORMS**
   a. Dossier checklist
   b. Dossier forms
   c. Price declaration form (D1, D2 & D3)
   d. Cost Comparison and Financial Implication (only for D2 & D3)
   e. Statement of Declaration

iv. **PART B: SUPPORTING DOCUMENTS**
   a. Copy of LOA
   b. Latest DCA approved product information leaflet and DCA indication certificate (upon request)
   c. Supporting Clinical Evidence (Effectiveness and Safety)
      - Evidence table
   d. Supporting Economic Evidence
      - Evidence table
      - BIA full report
   e. USB drive for softcopy of dossier (labelled with medicine names: generic and brand)

v. **OTHERS**: Sample of product (upon request)

3. CHECKLIST FOR DOCUMENTS

Table 11: Checklist for type of documents to be submitted

PROCESS	DOCUMENTS	
	HARDCOPY	SOFTCOPY
A) LOI SUBMISSION		
Dossiers D1 & D2		
• **Appendix 1A:** Pharmaceutical companies/ MOH facilities	-	/
Pharmaceutical companies: • URL/snapshot/document of reimbursement/formulary in at least two countries containing information on generic name, indication and approval • Sales report for six months (Example: summary of sales which contains information on date for first sale, quantity for public and private sectors without stating the name of facilities involved) • Executive summary of updated Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER) (Local safety report is preferred) • Summary and citation (Vancouver style) of the comparative effectiveness and/or safety studies (Head-to-head studies are highly preferred).	- - - -	/ / / /
MOH facilities: • Drug utilisation data	-	/
Dossier D3		
• **Appendix 1B:** MOH facilities	-	/
• CPG local/ international • Other relevant supporting document(s)	-	/ /
B) DOSSIER SUBMISSION (D1, D2 & D3) **One (1)** hardcopy and softcopy of documents should be submitted as listed below:		
• Checklists • Dossier forms	/ /	/ /
Supporting documents: • Copy of LOA • DCA approved product information leaflet • DCA indication certificate (upon request) • Full-text journal articles • Guidelines • BIA live excel sheet • BIA report (PDF and editable Word) • PSUR/PBRER (full report)	 / / / / - - / -	 / / / / / / / /
C) USB DRIVE (softcopy of documents**)**	**-**	/
D) SAMPLE OF PRODUCT (upon request)	**-**	**-**
E) DELISTING PROPOSAL (D4)		
• Dossier D4 form • Other relevant supporting document(s)	/	/

Note: *Any additional documents that are too voluminous (more than 20 pages) to be included in the hard copy can be provided in the electronic copy. Notes can be added to the hard copy to indicate this.*

4. CONTACT ADDRESS FOR THE MOHMF SECRETARIAT

The complete LOI, dossier and other supporting documents in the latest format, where applicable, should be submitted to:

Secretariat
Ministry of Health Medicines Formulary
Pharmacy Practice and Development Division
Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz
46200 Petaling Jaya, Selangor.

The Secretariat can be reached by email, cpfor@moh.gov.my for further enquiry and assistance.

REFERENCES

1. U.S. Food and Drug Administration. Drugs@FDA Glossary of Terms [Internet]. 2017 [cited 2023 Apr 5]. Available from: https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#D
2. National Cancer Institute. National Institutes of Health (US). [cited 2023 Apr 6]. Ayurvedic medicine. Available from: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/ayurvedic-medicine
3. National Pharmaceutical Regulatory Agency. Drug Registration Guidance Document (DRGD) [Internet]. 2023 Jan [cited 2023 Apr 5]. Available from: https://www.npra.gov.my/easyarticles/images/users/1047/DRGD%20Jan%202023/Complete-Drug-Registration-Guidance-Document-DRGD-3rd-Edition-4th-Revision-January-2023.pdf
4. Pharmaceutical Services Programme. Ministry of Health Malaysia. 2023 [cited 2023 Apr 5]. Ministry of Health Medicines Formulary (MOHMF). Available from: https://www.pharmacy.gov.my/v2/en/documents/ministry-health-medicines-formulary-mohmf.html
5. Control of Drugs and Cosmetics Regulations 1984 [Internet]. Available from: https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/control-drugs-and-cosmetics-regulations-1984-edited.pdf
6. WHO global report on traditional and complementary medicine 2019 [Internet]. Geneva: World Health Organization; 2019 [cited 2023 Apr 5]. Available from: https://apps.who.int/iris/bitstream/handle/10665/312342/9789241515436-eng.pdf?sequence=1&isAllowed=y
7. S.784 - Dietary Supplement Health and Education Act of 1994 [Internet]. Available from: https://www.congress.gov/bill/103rd-congress/senate-bill/784/text
8. CFR - Code of Federal Regulations Title 21 [Internet]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=314.3
9. Sale of Drugs Act 1952 (Revised - 1989) [Internet]. Available from: https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/sales-drug-act-1952-act-368.pdf
10. Fifty-first report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations [Internet]. Geneva: World Health Organization; 2017 [cited 2023 Apr 6]. (WHO technical report series;1003). Available from: https://apps.who.int/iris/bitstream/handle/10665/258720/9789241210034-eng.pdf?sequence=1&isAllowed=y
11. U.S. Food and Drug Administration. Generic Drugs: Questions & Answers | FDA [Internet]. 2021 [cited 2023 Apr 5]. Available from: https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers
12. World Health Organisation and Health Action International. Measuring medicine prices, availability, affordability and price components [Internet]. 2nd edition. Geneva: World Health Organization; 2008 [cited 2023 Apr 6]. Available from: https://apps.who.int/iris/bitstream/handle/10665/70013/WHO_PSM_PAR_2008.3_eng.pdf?sequence=1&isAllowed=y
13. Pan American Health Organization. Pharmaceutical situation in the Caribbean: fact book on Level I monitoring indicators - 2007 [Internet]. Washington, D.C.: Pan American Health Organization; 2010 [cited 2023 Apr 5]. Available from: https://iris.paho.org/bitstream/handle/10665.2/31218/9789275131312-eng.PDF?sequence=1&isAllowed=y
14. Medical Device Authority. Guidelines for implementation of medical device regulatory system: how to apply for medical device registration under Medical Device Act 2012 (Act 737) [Internet]. 2019 Mar [cited 2023 Apr 5]. Available from: https://portal.mda.gov.my/doclink/how-to-apply-for-medical-device-registration-under-medical-device-act-2012-third-

edition/eyJ0eXAiOiJKV1QiLCJhbGciOiJIUzI1NiJ9.eyJzdWIiOiJob3ctdG8tYXBwbHktZm9yLW1IZGljYWwtZGV2aWNlLXJlZ2lzdHJhdGlvbi11bmRlci1tZWRpY2FsLWRldmljZS1hY3QtMjAxMi10aGlyZC1IZGl0aW9uIiwiaWF0IjoxNjY2MDc5MDc4LCJleHAiOjE2NjYxNjU0Nzh9.ZC4ZYeOuw4o72nIRz0MIZ7X9Ys3x6eXbN8Qpg9VGNxs

15. Poisons Act 1952 (Revised-1989). [cited 2023 Apr 5]; Available from: https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/poisons-act-1952-act-366-edit-a1666-clean-1_0.pdf
16. Intellectual Property Corporation of Malaysia (MyIPO). Patent Basics [Internet]. [cited 2023 Apr 5]. Available from: https://www.myipo.gov.my/en/1814-2/?lang=en
17. The World Bank Group. World Bank Open Data [Internet]. [cited 2023 Apr 5]. Available from: https://data.worldbank.org/

APPENDICES

Appendix 1A: Letter of Intent Format (Dossiers D1 & D2)

A-FR-10/2

(Company/ Institution letter head) Date:

Secretariat
MOH Medicines Formulary
Pharmacy Practice and Development Division
Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz
46200 Petaling Jaya, Selangor

INTENT TO SUBMIT DOSSIER FOR LISTING OF MEDICINE INTO THE MOH MEDICINES FORMULARY

I/We* hereby submit this letter to notify our company's/facility's* intent to submit a full dossier for listing into the MOH Medicines Formulary (MOHMF). Please find below details of the medicine intended for listing:

Generic Name:		
Strength(s):		
Dosage Form(s):		
Proprietary Name (Brand):	*(only applicable for PRH)*	
Name & Address of Manufacturer:	*(only applicable for PRH)*	
Name & Address of Registration Holder:	*(only applicable for PRH)*	
DCA Registration Number:	MAL…	
DCA Approved Indication(s):		
Proposed indication(s) for the MOHMF *(Applicable for Dossier D1)*:		
Type of Dossier proposed to be submitted: *(Please tick where applicable)*		D1 (to list new medicine)
		D1 (to add indication)
		D2 (add dosage form/strength)
Resubmission:	YES/NO *(If yes, please state date of previous submission)*	
Justification for resubmission:	*Please address previous reason for rejection and state new information available for the resubmission. Please use attachment if necessary*	

*(Note: *where applicable)*

2. I/We* declare that the medicine has fulfilled all five (5) eligibility criteria listed in the Submission Guideline (as per Appendix 1a). I/We* agree if the product has been listed into the MOHMF (only applicable for pharmaceutical company):

i. the company has to issue a six-month notice before any product withdrawal from the market.
ii. the company has to provide one year utilisation data post-listing.

Thank you.

Yours sincerely,

……
Name:
Designation:
Telephone No.:
Email Address:

Contact Person (If different from signee)
Name:
Designation:
Telephone No.:
Email Address:

FIVE (5) ELIGIBILITY CRITERIA FOR MEDICINES INTENDED TO BE APPLIED FOR LISTING OF MEDICINES INTO THE MOH MEDICINES FORMULARY

NO.	CRITERIA	YES/NO	COMMENT	FOR SECRETARIAT USE
1.	Medicine (new chemical entity) must be registered with the Drug Control Authority (DCA) in Malaysia for at least 12 months. ***Note**: Only applicable for dossier D1 (new medicine)*			
2.	Indication(s) must be approved by the DCA in Malaysia.			
3.	The medicine (and its indication(s) applied for listing) is listed in the reimbursement list / national formulary in at least two (2) countries. *State the country referenced (any country) and provide supporting evidence (URL/snapshot/ document of reimbursement containing information on generic name, indication and approval – in English/translated into English)*			
4.	Medicine must have been used for at least 6 months in Malaysia post DCA registration: *Please provide the following documents:* • *Sales report for six months (Example: summary of sales which contains information on date for first sale, quantity for public and private sectors without stating the name of facilities involved)* • *Executive summary of updated Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER) (Local safety report is preferred)*			
5.	Medicine must have therapeutic and/or safety advantage supported by scientific evidence. *Please provide summary and citation (Vancouver style) of the comparative effectiveness and/or safety studies. Head-to-head studies are highly preferred.*			

FOR SECRETARIAT USE		
RECEIPT DATE		Comment:
SCREENING DATE		
SCREENED BY		

Appendix 1B: Letter of Intent Format (Dossier D3)

A-FR-31/2

(Institution letterhead) Date:

Secretariat
MOH Medicines Formulary
Pharmacy Practice and Development Division
Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz
46200 Petaling Jaya, Selangor

INTENT TO SUBMIT DOSSIER D3 TO CHANGE PRESCRIBER CATEGORY OF MEDICINE LISTED IN THE MOH MEDICINES FORMULARY

I/We* hereby submit this letter to notify our intent to submit a full dossier to change prescriber category of medicine listed in the MOH Medicines Formulary. Please find below details of the medicine intended:

Generic Name:				
Strength(s):				
Dosage Form(s):				
Indication(s) as in MOHMF:				
Proposed indication(s) for amendment:				
Prescriber category:	**Current:**		**Proposed:**	
Rationale for application:	*Please justify the request to change prescriber category*			

2. I/We* do sincerely declare herewith that to my best knowledge and professional responsibility, all the information above is accurate at the time of submission.

Thank you.

Yours sincerely,

……
Name:
Designation:
Telephone No.:
Email Address:

Contact Person
Name:
Designation:
Telephone No.:
Email Address:

A-FR-11/3

Appendix 2: Pre-Submission Meeting Request Form

Type of Pre-Submission Meeting Requested (Please tick)

☐ **Early Pre-Submission Meeting (before submission of LOI)**

☐ **Standard Pre-Submission Meeting (after the issuance of LOA)**

Section 1: Dossier Background Information	
Background Information Requested	**Details**
Applicant (Company name)	*Insert company name*
Medicine name	*Insert the non-proprietary name and brand name*
Route of administration	*Insert the route of administration (e.g. oral, intravenous, subcutaneous, inhalation)*
Dosage form and strength(s)	*Provide a list of all the dosage forms and strengths of the drug*
Approved indication(s)	*Indication(s) approved by *DCA (Please state DCA Registration number and registration date)* *Proposed indication(s) to be listed in the MOHMF*
Trial information	*Provide a brief overview of pivotal trial(s) (i.e. study design, sample size, population description, intervention & comparator details, primary and key secondary endpoints)*
Comparator(s)	*Provide a list of the other treatment(s) and/or procedure(s) used for the condition (both MOHMF and non-MOHMF drugs)*

*DCA = Drug Control Authority, Malaysia

Section 2: Details of Pre-submission Meeting Requested	
Date	*Insert the proposed date of the meeting*
Time	*Insert the proposed time of the meeting*
Name of officers attending the meeting (Company)	*Name the officers that are going to attend the meeting (maximum three (3) officers)*
Questions to be asked/ Matters to be discussed	*State in detail all the questions/ matters to be discussed in the meeting.*

Section 3: Additional Information *(if applicable)*
Is the drug indicated for a relatively small patient population?
Response: ☐ **Yes** ☐ **No** **Supporting information:**
Are there a limited number of clinical trials and do they have small sample sizes?
Response: ☐ **Yes** ☐ **No** **Supporting information:**
Does the treatment have a higher cost relative to appropriate comparator(s)?
Response: ☐ **Yes** ☐ **No** **Supporting information:**
Do you have questions regarding the appropriate type of economic analysis to submit?
Response: ☐ **Yes** ☐ **No** **Details**: *Kindly specify /provide details of your enquiry.*

Please use attachment if required

Contact Details	
Contact Person	**Details**
Name	
HP/ Office Number	
Email Address	
Date	

Appendix 3A: Checklist for Dossier D1

A-FR-32/2

CHECKLIST FOR DOSSIER D1	
Tick (√) for the type of dossier to be submitted	
	Proposal to List New Medicine(s) into the MOH Medicines Formulary
	Proposal to List New Indication(s) for Existing Medicines in the MOH Medicines Formulary
MEDICINE NAME:	
COMPANY NAME:	

NO	PARTICULARS	TICK (√)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
SECTION 1: MEDICINE INFORMATION				
A. Medicine Particulars				
1.	Generic name of medicine (including dosage form, strength, concentrations)			
2.	Proprietary name			
3.	Registration holder			
4.	Manufacturer			
5.	DCA registration number and date			
6.	i. DCA approved indication(s)			
	ii. Proposed indication for the MOHMF			
	iii. Proposed prescribing restriction(s) of use (if any)			
7.	Declaration of products containing animal sources			
8.	Information on formulary/ reimbursement in other countries with supporting documents			
B. Clinical & Pharmacological Information				
1.	Dosing and administration (including subpopulation doses)			
2.	Proposed course of treatment (duration) and repeats (if any)			
3.	Name of principal pharmacological/ therapeutic class			
4.	Concomitant therapies (if any)			
5.	Co-administered therapies for side-effects (if any)			
6.	Contraindications			
7.	Adverse reactions			
8.	Warnings/ Precautions			
9.	Interactions (Medicine/ Food/ Disease)			

NO	PARTICULARS	TICK (√)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
C. Special Device (if any)				
1.	Device requirement			
2.	Supply of device			
D. Medicine and Related Treatment Costs				
1.	Price per unit (SKU)			
2.	Number of dosage units per day or per cycle			
3.	Average duration of treatment in days or cycles per year			
4.	Total medicine cost per patient per year			
5.	Additional cost per patient per year			
6.	Total annual cost per patient			
Supporting document(s) for Section 1:				
7.	Medicine Price Declaration Form (Appendix 6)			
8.	Most recent DCA indication certificate (Upon request)			
9.	DCA approved product information leaflet			
SECTION 2: RATIONALE FOR APPLICATION AND COMPARATORS				
1.	Overview of disease			
2.	Rationale for listing			
3.	Details on rationale for the application			
4.	Existing medicine(s) / comparator(s) for the same/similar indication(s)			
5.	Existing medicine(s) / comparator(s) in same therapeutic class			
6.	Non-pharmacological alternatives (if any)			
7.	Non-formulary comparators (if any)			
8.	Existing medicine(s)/ comparator(s) which have off-label use for the same/similar indication(s)			
SECTION 3: SUPPORTING CLINICAL EVIDENCE (EFFECTIVENESS AND SAFETY)				
1.	Summary of systematic search strategies for evidence			
2.	Evidence tables for each research article			
3.	Supporting evidence for efficacy/ effectiveness and safety (softcopy)			
4.	Clinical trial/ study reports conducted in Malaysia (if any) (softcopy)			
5.	Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)/Post Marketing Safety Report – Malaysia) (softcopy)			

NO	PARTICULARS	TICK (√)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
SECTION 4: SUPPORTING ECONOMIC EVIDENCE				
1.	Economic studies / reports (if any)			
2.	Evidence tables for each economic study			
3.	Local economic evaluation (if any) a) Report b) Live MS Excel format (softcopy)			
4.	Budget impact analysis (**mandatory**) a) Report b) Live MS Excel format (softcopy)			
OTHERS				
1.	Applicant Statement of Declaration – Signature, stamp and contact details of the proposer (Appendix 8A)			
2.	Softcopy of dossier (including research articles and economic models if any) in USB drive			
3.	Sample of drug (one unit only with packaging/ box) if requested			
4.	List of references in Vancouver style			
5.	Relevant treatment guidelines, if available (softcopy)			
6.	**Payment Information:** Bank draft/ money order/postal order made payable to '***KETUA SETIAUSAHA, KEMENTERIAN KESIHATAN MALAYSIA'.*** ( ) RM 5,000.00 [Proposal to list new medicine(s) into the MOH Medicines Formulary] ( ) RM 3,000.00 [Proposal to list new indication(s) for existing medicines in the formulary list] Bank draft no./money order no./postal order no.: _____ *Please refer to the guideline for details on the fee.*			

Filled in by: *Please state name and contact number*

Date:

NOTE:

- *Incomplete applications will not be processed.*
- *Please provide **one (1) hardcopy and softcopy** of dossier form with supporting documents (DCA indication certificate (upon request), journal articles, product information leaflet, and BIA report). Any other supporting documents that are more than 20 pages shall be submitted in softcopy only (with note in the dossier/ checklist).*
- *Kindly refer to **Instructions to Applicant** section in this guideline for reference.*

FOR SECRETARIAT USE		
Dossier receipt date		**Comments:**
Dossier complete date		
Dossier reference no.		
Checked by		

A-FR-12/3

Appendix 3B: Dossier D1 Form

SECTION 1: MEDICINE INFORMATION

Instruction:

- Applicant should provide detailed information about the medicines as required in the form below.
- The information should be obtained from official reliable sources for example medicine monograph or product information leaflet.
- The latest DCA approved product information leaflet and DCA indication certificate (if requested) must be attached.
- Applicant is required to provide sample of medicine upon request from the Secretariat.

A. MEDICINE PARTICULARS		
1.	Generic Name [specify dosage form(s) & strength(s)/ concentration(s)]	*Provide full generic name of the medicine.* *Use a different line for each dosage form and strength/ concentration (if any).*
2.	Proprietary Name	*State the medicine trade name marketed in Malaysia.*
3.	Registration Holder	*State company's name and address.*
4.	Manufacturer	*State company's name and address.*
5.	DCA Registration No.	*State DCA registration number and date of registration of the medicine.* *(Please provide DCA approval letter/ Latest DCA indication certificate; upon request).*
6.	i) DCA Approved Indication(s)	*List all DCA approved indication(s) of the medicine.*
	ii) Proposed Indication for the MOH Medicines Formulary (MOHMF)	*State indication that will be proposed into the MOHMF.*
	iii) Proposed Prescribing Restriction(s) of Use (if any)	*State prescribing restriction(s) proposed to be imposed when prescribing the medicine.* *(Example: age, sex, conditions, severity of disease, stages of treatment etc.)*
7.	Declaration of Products Containing Animal Sources	*State the origins of the ingredients used in preparing the medicine.*

<table>
<tr><td>8.</td><td>Formulary/ Reimbursement in Other Countries</td><td>
<table>
<tr><th>Country</th><th>Status of Listing</th><th>Year Listed</th><th>Approved Indication(S)</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
</table>
State the name of the country where the medicine is reimbursed. Fill in the year the medicine was listed and state the approved indication(s).
Attach supporting evidence (please translate the document into English, if the original document is in languages other than Malay or English).
</td></tr>
</table>

<table>
<tr><th colspan="3">B. CLINICAL AND PHARMACOLOGICAL INFORMATION</th></tr>
<tr><td rowspan="6">1.</td><td>Dosing and Administration (Dose, Frequency, Route of Administration)</td><td>State the dose, frequency and route of administration for the medicine in all population groups for each indication applied.</td></tr>
<tr><td>a) Adult Dose</td><td></td></tr>
<tr><td>b) Paediatric Dose (if applicable)</td><td></td></tr>
<tr><td>c) Dose in Renal Impairment</td><td></td></tr>
<tr><td>d) Dose in Liver Failure</td><td></td></tr>
<tr><td>e) Others (if any)</td><td></td></tr>
<tr><td>2.</td><td>Proposed Course of Treatment (Duration) and Repeats (if any)</td><td>State the recommended duration of treatment and/or treatment cycle. State 'life-long' if the medicine will be used continuously by the patient.</td></tr>
<tr><td>3.</td><td>Name of Principal Pharmacological/ Therapeutic Class</td><td>State the principal pharmacological/therapeutic class of the medicine and its Anatomical Therapeutic Classification (ATC).</td></tr>
<tr><td>4.</td><td>Concomitant Therapies (if any)</td><td>If the medicine is to be used in combination with other therapies, state the concomitant therapies with the dosage, frequency, and duration.
State all the concomitant therapies for each proposed indication.</td></tr>
<tr><td>5.</td><td>Co-administered Therapies to Manage Side-Effects (if any)</td><td>If the use of this medicine results in the need for co-administration of other therapies to manage the side effects of the applied medicine, state these additional therapies (with dosage, frequency, and duration).</td></tr>
<tr><td>6.</td><td>Contraindications</td><td>State all contraindications when taking this medicine as approved by DCA.</td></tr>
</table>

7.	Adverse Reactions	*State all adverse reactions.* *Provide Periodic Safety Update Report (PSUR) or Periodic Benefit-Risk Evaluation Report (PBRER).*
8.	Warnings/ Precautions	*State all warnings and precautions.* *State any changes that have been made since marketing authorisation received from DCA.*
9.	Interactions (Medicine/ Food/ Disease)	*State the significant interaction(s) with medicine/ food/ disease.*

C. SPECIAL DEVICE (if any)		
1.	Device Requirement	*State if the medicine needs special device. If yes, please provide detailed information.*
2.	Supply of Device	*State the supply mechanism of the above said device (e.g.: Free of charge, to be purchased separately)*

D. MEDICINE AND RELATED TREATMENT COSTS		
1.	Price per Unit (SKU) (RM): ***(a)***	*State the nett price to MOH institutions, inclusive of all fees. Submit details as required in Medicine Price Declaration Form (Appendix 6).*
2.	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.*
3.	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.*
4.	Total Medicine Cost per Patient per Year ***(d)*** ***d = a x b x c***	*This can be calculated by multiplying* ***a, b, and c.***
5.	Additional Cost per Patient per Year ***(e)*** Data Sources Not Limited to the MOH Facilities (Example: MOHE, MOD or Private Setting). Data Sources Must Be Reported.	*List all potential additional costs. 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.* *If no published data is available, estimates can be used. However, estimates need to be justified.*
6.	Total Annual Cost per Patient ***(f)***	***f = (d + e)***

SECTION 2: RATIONALE FOR APPLICATION AND COMPARATORS

A. OVERVIEW OF THE DISEASE AND CURRENT MANAGEMENT

Please provide:

- *An overview of the disease and the patient population that the product is targeted for;*
- *Data on disease prevalence and epidemiology in Malaysia;*
- *Global epidemiology data may also be included;*
- *Brief overview on the current disease management;*
- *Other relevant information.*

B. RATIONALE FOR LISTING APPLICATION

Tick(√) the main reason(s) to list the product :	
	New innovator medicine
	Has therapeutic advantage over an existing medicine(s)
	A cheaper alternative to an existing medicine(s)
	Insufficiently treated condition
	Improve compliance
	Others (please specify):

Details on rationale for the application:

Explain in detail the rationale/justifications to list this medicine/indication.

- *State the advantages and differences of the proposed medicine over the available therapies in the MOHMF.*
- *State the place of therapy for this new medicine in the disease treatment (e.g. first line, second line etc.)*
- *State the specific patient population that will benefit from this medicine (if any).*

C. EXISTING TREATMENT/ MEDICINE(S)

EXISTING TREATMENT/ MEDICINE(S) FOR THE SAME/ SIMILAR INDICATION(S) IN MOH MEDICINES FORMULARY *[Specify Strength & Dosage Form]*	
Existing medicine(s)/ comparator(s) for the same/similar indication(s)	*List all the existing medicine(s) in MOHMF with the same/similar indication(s). Provide medicine names, strengths, and dosage forms.*
Existing medicine(s)/ comparator(s) in the same therapeutic class	• *List all the existing medicine(s) in MOHMF with the same/similar therapeutic class.* • *Provide medicine names, strengths and dosage forms.*
Non-pharmacological alternatives (if any)	*List all non-pharmacological therapies, which can be used for the same indication (if any).*
Non-formulary comparators (if any)	*List the medicine(s) with the same/ similar indication(s) or therapeutic class that are not listed in the MOHMF.*
Existing medicine(s)/ comparator(s) which have off-label use for the same/similar indication(s)	*List existing medicine(s)/ comparator(s) which have off-label use for the same/similar indication(s)*

Appendix 4A: Checklist for Dossier D2

A-FR-33/2

CHECKLIST FOR DOSSIER D2	
DOSSIER 2 (D2): PROPOSAL TO ADD DOSAGE FORM / STRENGTH OF MEDICINES LISTED IN THE MOHMF	
MEDICINE NAME:	
COMPANY NAME:	

NO	PARTICULARS	TICK (√)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
SECTION 1: MEDICINE INFORMATION				
A.	**Medicine Particulars**			
1.	Generic name			
	i. Proposed dosage form(s) & strength(s)/ concentration(s)			
	ii. Existing medicine in the MOHMF			
2.	Proprietary name			
3.	Registration holder			
4.	Manufacturer			
5.	DCA Registration No.			
6.	i. DCA approved indication(s)			
	ii. Indication(s) in the MOHMF			
	iii. Proposed prescribing restriction of use (if any)			
7.	Declaration of products containing animal sources			
B.	**Clinical & Pharmacological Information**			
1.	Dosing and administration (including subpopulation doses)			
2.	Proposed course of treatment (duration) and repeats if any			
3.	Concomitant therapies (If any)			
4.	Co-administered therapies to manage side-effects (if any)			
5.	Contraindications			
6.	Adverse reactions			
7.	Warnings / Precautions			
8.	Interactions (Medicine/ Food/ Disease)			
C.	**Special Device (if any)**			
1.	Device requirement			
2.	Supply of device			
D.	**Medicine and Related Treatment Costs**			
1.	Medicine Price Declaration Form (Appendix 6)			

NO	PARTICULARS	TICK (√)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
2.	Cost comparison and financial implication of proposed drug vs. comparator/ existing medicine in the MOHMF (Appendix 7)			
Other supporting documents:				
1.	DCA approval letter/ Certificate of renewal (with full indication)			
2.	DCA indication certificate (upon request)			
3.	DCA approved product information leaflet			
SECTION 2: RATIONALE FOR APPLICATION AND COMPARATORS				
1.	Overview of disease and current management			
2.	Rationale for listing			
3.	Details on rationale for the application			
SECTION 3: SUPPORTING CLINICAL EVIDENCE (EFFECTIVENESS AND SAFETY)				
1.	Summary of systematic search strategies for evidence			
2.	Evidence tables for each research article			
3.	Supporting evidence for efficacy / effectiveness and safety (softcopy)			
4.	Clinical trial/ study reports conducted in Malaysia (if any) (softcopy)			
5.	Executive summary of Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)/ Post Marketing Safety Report –Malaysia) (softcopy)			
SECTION 4: SUPPORTING ECONOMIC EVIDENCE				
1.	Economic studies / reports (if any)			
2.	Evidence tables of economic studies			
OTHERS				
1.	Applicant Statement of Declaration – Signature, stamp and contact details of the proposer (Appendix 8A)			
2.	Softcopy of dossier (including research articles and economic models if any) in USB drive			
3.	Sample of drug (one unit only with packaging/ box) if requested			
4.	List of references in Vancouver style			
5.	Relevant treatment guidelines, if available (softcopy)			

NO	PARTICULARS	TICK (√)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
6.	**Payment Information:** Bank draft/ money order/postal order made payable to '***KETUA SETIAUSAHA, KEMENTERIAN KESIHATAN MALAYSIA'.*** ( ) RM 2,000.00 [Proposal to add dosage form/strength of medicines listed in the MOH Medicines Formulary] Bank draft no./ money order no./ postal order no.: _____ *Please refer to the guideline for details on the fee.*			

Filled in by: *Please state name and contact no.*

Date :

NOTE:

- *Incomplete applications will not be processed.*
- *Please provide **one (1) hardcopy and softcopy** of dossier form with supporting documents (DCA indication certificate (upon request), journal articles, product information leaflet, and etc.). Any other supporting documents that are more than 20 pages shall be submitted in softcopy only (with note in the dossier/ checklist).*
- *Kindly refer to **Instructions to Applicant** section in this guideline for reference.*

FOR SECRETARIAT USE		
Dossier receipt date		**Comments:**
Dossier complete date		
Dossier reference no.		
Checked by		

A-FR-13/3

Appendix 4B: Dossier D2 Form

To Add Dosage Form/Strength of Medicines Listed in the MOH Medicines Formulary.

SECTION 1: MEDICINE INFORMATION

Instructions

- Applicant should provide detailed information about the medicine as required in the form below.
- The sample of medicine should be provided upon request by the Secretariat.

A. MEDICINE PARTICULARS		
1.	Generic Name [specify dosage form(s) & strength(s)/ concentration(s)]	*Proposed Medicine:* *Provide full generic name of the medicine.* *Use a different line for each dosage form and strength / concentration (if any)*
		Existing medicine in the MOHMF: *State all the dosage forms and strengths currently available in the MOHMF.*
2.	Proprietary Name	*State the medicine trade name marketed in Malaysia*
3.	Registration Holder	*State company's name and address*
4.	Manufacturer	*State manufacturer's name and address*
5.	DCA Registration No.	*State DCA registration number and registration date.*
6.	i) Approved Indication(s)	*a) DCA Approved Indication(s):* *List all the DCA approved indication(s) of the medicines.* *Upon request, latest DCA indication certificate must be submitted as reference*
		b) Indication(s) in the MOHMF: *State current indication(s) listed in the MOHMF.*
	ii) Proposed Prescribing Restriction of Use (if any)	*State prescribing restriction(s) proposed to be imposed when prescribing the medicine.* *(Example: age, sex, conditions, severity of disease, stages of treatment etc.)*
7.	Declaration of Products Containing Animal Sources	*State the origins of the ingredients used in preparing the medicines.*

B. CLINICAL AND PHARMACOLOGICAL INFORMATION		
1.	Dosing and Administration (dose, frequency, route of administration)	*State the dose, frequency, and route of administration for the medicine in all population groups for each indication applied.*
	a) Adult Dose	
	b) Paediatric Dose (if applicable)	
	c) Dose in Renal Impairment	
	d) Dose in Liver Failure	
	e) Others (if any)	
2.	Proposed Course of Treatment (Duration) and Repeats If Any	*State the recommended duration of treatment and/or treatment cycle (if any). State 'life-long' if the medicine will be used continuously by patient.*
3.	Concomitant Therapies (If any)	*If the medicine is to be used in combination with other therapies, state the concomitant therapies with the dosage, frequency, and duration.* *If the medicine is used for more than one proposed indication, state the concomitant therapies by indications.*
4.	Co-administered Therapies to Manage Side-Effects (if any)	*If the use of this medicine results in the need for co-administration of other therapies to manage the side-effects of the applied medicine, state these additional therapies (with dosage, frequency, and duration)*
5.	Contraindications	*State all contraindications when taking this medicine as approved by DCA.*
6.	Adverse Reactions	*State the significant adverse reactions, references as approved by DCA and Post Marketing Surveillance reports available.*
7.	Warnings/ Precautions	*State all warnings and precautions associated with the medicine as approved by DCA and references.* *State any changes have been made since marketing authorisation approved from DCA.*
8.	Interactions (Medicine/ Food/Disease)	*State the significant interaction(s) with medicine/ food/ disease with complete reference details.*

C. SPECIAL DEVICE (if any)		
1	Device Requirement	*State if the medicine needs special device. If yes, please provide detailed information.*
2	Supply of Device	*State the supply mechanism of the above said device (e.g.: Free of charge, to be purchased separately).*

D. MEDICINE AND TREATMENT RELATED COSTS

- Details on costs of medicines and any other costs related to the proposed treatment should be stated using the format in **Appendix 7** including cost comparison between new proposed medicine and existing medicine.
- The estimated budget implications of introducing the new dosage forms/ strengths in MOH setting should be stated.

SECTION 2: RATIONALE FOR APPLICATION AND COMPARATORS

A. OVERVIEW OF THE DISEASE AND CURRENT MANAGEMENT

Please provide:

- *An overview of the disease and the patient population that the product is targeted for;*
- *Data on disease prevalence and epidemiology in Malaysia;*
- *Brief overview on the current disease management;*
- *Other relevant information.*

B. RATIONALE FOR LISTING

Tick the main reason(s) to list the product:	
	Has therapeutic advantage over an existing medicine(s)
	A cheaper alternative to an existing medicine(s)
	Insufficiently treated condition
	Improve compliance
	New innovative medicine
	Others (specify below):

Details on rationale of the application:

- *Provide justification for listing this dosage form/ strength. (Include advantages and differences of the proposed dosage form/ strength over the available therapies in the MOHMF).*
- *State the proposed place of therapy for this new dosage form/strength in the disease treatment (e.g. first line, second line etc.)*
- *State specific patient population that will benefit from the dosage form/strength (if any).*

Appendix 5A: Checklist for Dossier D3

A-FR-34/2

CHECKLIST FOR DOSSIER D3	
DOSSIER 3 (D3): PROPOSAL TO CHANGE CATEGORY OF PRESCRIBER OF MEDICINES IN THE MINISTRY OF HEALTH MEDICINES FORMULARY	
MEDICINE NAME:	
FACILITY:	

NO	PARTICULARS	TICK (√)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
SECTION 1: MEDICINE INFORMATION				
A.	**Medicine particulars**			
1.	Generic name			
2.	Indication(s) as in the MOHMF			
3.	Proposed indication(s) for amendment			
4.	Currently available brands, product registration holder, and manufacturer			
5.	Proposed prescribing restriction (if any):			
6.	Method of purchase			
7.	Prescriber category:			
	i. Existing prescriber category in the MOHMF			
	ii. Proposed prescriber category			
8.	Existing medicines in the MOHMF for the proposed prescriber category			
9.	Alternative to replace (if any)			
B.	**Clinical & Pharmacological Information**			
1.	Dosing and administration (including subpopulation doses)			
2.	Proposed course of treatment (duration) and repeats (if any)			
3.	Concomitant therapies (if any)			
4.	Co-administered therapies to manage side-effects			
C.	**Special Device (if any)**			
1.	Device requirement			
2.	Supply of device			
D.	**Medicine and Treatment Related Costs**			
1.	Medicine Price Declaration Form (Appendix 6)			
2.	Cost comparison and financial implication of proposed drug vs. comparator/ existing medicine in the MOHMF (Appendix 7)			
Other Supporting Documents:				
1.	DCA approved product information leaflet			

NO	PARTICULARS	TICK (√)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
SECTION 2: RATIONALE FOR APPLICATION				
1.	Rationale for the proposal			
2.	Details on rationale for the application			
SECTION 3: SUPPORTING CLINICAL EVIDENCE (EFFECTIVENESS AND SAFETY)				
1.	Summary of systematic search strategies for evidence			
2.	Evidence tables for each research article			
3.	Supporting evidence for effectiveness and safety (softcopy)			
4.	Clinical trial/ study reports conducted in Malaysia (if any) (softcopy)			
OTHERS:				
1.	Applicant Statement of Declaration – Signature, stamp and contact details of the proposer			
2.	Signature and stamp from: a. Head of Department/Unit; b. Head of Pharmacy Department/Unit; c. Head of Institution/Facility; and d. Chairperson of State Drugs & Therapeutic Committee / Chairperson of DWC, MOH			
3.	Softcopy of dossier (including research articles and economic models if any) in USB drive			
4.	List of references in Vancouver style			
5.	Relevant treatment guidelines, if available (softcopy)			

Filled in by: Please state name and contact no.
Date :

NOTE:

- *Incomplete applications will not be processed.*
- *Please provide **one (1) hardcopy and softcopy** of dossier form with supporting documents (DCA indication certificate (upon request), journal articles, product information leaflet, and etc.). Any other supporting documents that are more than 20 pages shall be submitted in softcopy only (with note in the dossier/ checklist).*
- *Kindly refer to **Instructions to Applicant** section in this guideline for reference.*

FOR SECRETARIAT USE		
Dossier receipt date		**Comments:**
Dossier complete date		
Dossier reference no.		
Checked by		

A-FR-14/3

Appendix 5B: Dossier D3 Form

To Change Category of Prescriber of Medicines in the MOH Medicines Formulary

SECTION 1: MEDICINE INFORMATION

Instructions

- Applicant should provide detailed information about the medicine as required in the form below.

A. MEDICINE PARTICULARS			
1.	Generic Name [specify pharmaceutical form(s) & strength(s)/ concentration(s)]	*Provide full generic name as available in the MOHMF.*	
2.	Indication(s) as in the MOH Medicines Formulary	*State all the indication(s) listed in the MOHMF*	
3.	Proposed Indication(s) for Amendment	*State the corresponding indication(s) of the medicine proposed to be changed category of prescriber in MOHMF.*	
4.	Currently Available Brands, Product Registration Holder, and Manufacturer	*State the trade name of the medicine, product registration holder and the manufacturer. For non-patented medicine, state the generics that are available.*	
5.	Proposed Prescribing Restriction (if any):	*State any prescribing restriction(s) proposed to be imposed when prescribing the proposed medicine.* *(E.g. age, sex, conditions, severity of disease, stages of treatment etc.)*	
6.	Method of Purchase *Tick (√) where applicable*		Central Contract
			APPL
			Local Purchase
7.	Prescriber Category	Existing prescriber category in the MOHMF:	
		Proposed prescriber category:	
8.	Existing Medicines in the MOHMF for the Proposed Prescriber Category	*State alternatives in the MOHMF with the same indication and proposed prescriber category.*	
9.	Is the Medicine a Replacement for Existing Alternative in the MOHMF? (if any)	No	Yes: …… *(Suggest medicine(s) that can be replaced. Please fill in Dossier D4 for deletion)*

B. CLINICAL AND PHARMACOLOGICAL INFORMATION		
1.	Dosing and Administration (Dose, Frequency, Route of Administration)	*State the dose, frequency and route of administration for the medicine I n all population groups for each indication applied.*
	f) Adult Dose	
	g) Paediatric Dose (if applicable)	
	h) Dose in Renal Impairment	
	i) Dose in Liver Failure	
	j) Others (if any)	
2.	Proposed Course of Treatment (duration) and Repeats (if any)	*State the recommended duration of treatment and treatment cycle (if any).* *State 'life-long' if the medicine will be used continuously by patient.*
3.	Concomitant Therapies (if any)	*If the medicine is to be used in combination with other therapies, state the concomitant therapies with the dosage, frequency, and duration.* *If the medicine is used for more than one proposed indication, state the concomitant therapies by indication.*
4.	Co-administered Therapies to Manage Side-Effects (if any)	*If the use of this medicine results in the need for co-administration of other therapies to manage the side-effects of the applied medicine, state these additional therapies (with dosage, frequency, and duration)*

C. SPECIAL DEVICE (if any)		
1.	Device Requirement	*State if the medicine needs special device. If it does, please provide detailed information.*
2.	Supply of Device	*If any*

D. MEDICINE AND TREATMENT RELATED COSTS

- Details on costs of medicines and any other costs related to the proposed treatment should be stated using the format in **Appendix 7** including cost comparison between new proposed medicine and existing medicine.
- The estimated budget implications of introducing the new dosage forms/ strengths in MOH setting should be stated.

SECTION 2: RATIONALE FOR APPLICATION

Tick the main reason(s) for the proposal:	
	Has therapeutic advantage over an existing medicine(s)
	A cheaper alternative to an existing medicine(s)
	Improve compliance
	Safety issues
	Others (specify below):

Details on rationale for the application:

- *Provide justification to change prescriber category.*
- *State the proposed place of therapy for this change in the disease treatment (Example: first line, second line etc.)*
- *State specific patient population who will benefit from this change (if any).*

A-FR-17/3

Appendix 6: Medicine Price Declaration Form

MEDICINE PRICING DETAILS			For Secretariat Use
1.	Type of Dossier	(D1/D2/D3)	
2.	Generic Name [specify dosage form(s) & strength(s)/ concentration (s)]		
3.	Proprietary Name		
4.	Product Registration Holder		
5.	Manufacturer & Country of Origin		
6.	Packaging Size		
7.	Price Per Packaging (RM) (Inclusive of e-Perolehan Fee)		
8.	Price Per Unit (SKU) (RM) (Inclusive of e-Perolehan Fee)		
9.	Public Wholesale Price per unit **(RM)** in TWO ASEAN countries*	1. 2.	
10.	Public Wholesale Price per unit **(RM)** in TWO ***peer / ***similar economic status* Countries from Other Region*	1. 2.	
11.	Public Wholesale Price per unit **(RM)** in Country of Origin*		
12.	Patent Validity Date		

* Not applicable for D3 (multisource/generic medicines)
** Country with similar income level as Malaysia based on classification by World Bank

AUTHORISED SIGNATORY
I, the undersigned, declare herewith that to my best knowledge and professional responsibility all information submitted within this dossier is complete and correct.
Signature: …… Date: ……
Name of Officer: …… Contact Number: ……
Company's Stamp: Email Address: ……

NOTE:

i. Price per unit quoted in this document shall be:
   - Net Price (inclusive of agents' commission). Purchase price of MOH health facility after the listing in MOH Medicines Formulary must not exceed the price quoted.
   - Price per unit quoted must be in lowest measuring unit (Example: tablet, vial, canister, capsule, prefilled syringe) for the relevant medicine(s) and any bid price scheme is not permitted.
   - The quoted price is valid for two (2) years from the date of listing of medicine(s) in the MOH Medicines Formulary.

ii. Notification on the medicine price listed in MOH Medicines Formulary will be issued by Medicine Price Management Branch, Pharmacy Practice and Development Division.

iii. Any offers for patient assisted programme should be explicitly declared and detailed.

A-FR-35/2

Appendix 7: Cost Comparison and Financial Implication

(For Dossiers D2 and D3)

COST COMPARISON [*please add more columns below if there is more than one comparator*]			
		New Drug **[Please state name of drug]**	**Current Drug/Comparator** **[Please state name of drug]**
a	Cost per dosage unit *Nett price to MOH hospital, inclusive of agent fees*	RM	RM
b	Number/average number of dosage units administered per day/cycle State the number (or average number) of dosage units administered per day or per cycle		
c	Average duration of treatment in days/cycle *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.*		
d	Total cost per patient per year ***d = a x b x c***	RM	RM
e	**Additional cost per patient per year, if it is possible to calculate *Data sources not limited to the MOH facilities (e.g. MOHE, MOD or private setting). Data sources must be reported. List all potential additional costs. 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.* *If no published data is available, estimates can be used. However, estimates need to be justified.*	RM	RM
f	Total annual cost per patient ***f =(d+e**)***	RM	RM
g	Expected number of patients per year (where applicable)		
	i) Institution		
	ii) State		
	iii) Country [MOH]		

FINANCIAL IMPLICATION			
Annual cost (f x g)	**New Drug [RM]**	**Current [RM]**	**Difference [RM]**
i) Institution			
ii) State			
iii) Country [MOH]			

A-FR-36

Appendix 8A: Applicant Statement of Declaration (Dossiers D1 & D2)

(Company/ Institution letter head) Date:

Secretariat
MOH Medicines Formulary
Pharmacy Practice and Development Division
Ministry of Health Malaysia
Lot 36 Jalan Profesor Diraja Ungku Aziz
46200 Petaling Jaya, Selangor

STATEMENT OF DECLARATION

I, _____ (*name of applicant*) (NRIC No._____) do solemnly and sincerely declare the following:

1. That I am _____(*position in company/facility*) and am duly authorized to affirm this statement of declaration on behalf of the company/facility;
2. I do sincerely declare herewith that to my best knowledge and professional responsibility all the information submitted within this dossier is complete and accurate at the time of submission.
3. I acknowledge the Secretariat has the right to withhold or suspend evaluation in the event any amendment on the information submitted in the dossier is not notified.
4. I agree that the company has to issue a six-month notice before any product withdrawal from the market if the product has been listed into the MOH Medicines Formulary (only applicable for pharmaceutical companies).
5. I agree that the company has to provide one year utilisation data post-listing.

Subscribed and solemnly declared by the above named

at ……..... *(place)*)
in the State of …….....)
this …….. day (*date*) of …….. (*month*) 20……. (*year*))
Contact No : ……..... (*h/p*))
……(*office*))
Email address: ……...)
)……...
(signature of declarant, company's/facility's stamp with address)

A-FR-37/2

Appendix 8B: Applicant Statement of Declaration (Dossier D3)

(Institution letter head) Date:

Secretariat
MOH Medicines Formulary
Pharmacy Practice and Development Division
Ministry of Health Malaysia
Lot 36 Jalan Profesor Diraja Ungku Aziz
46200 Petaling Jaya, Selangor

STATEMENT OF DECLARATION

I, _____ (*name of applicant*) (NRIC No._____) do solemnly and sincerely declare the following:

1. That I am _____ (*position in institution/ committee*) and am duly authorized to affirm this statement of declaration on behalf of the institution/ committee;
2. I do sincerely declare herewith that to my best knowledge and professional responsibility all the information submitted within this dossier is complete and accurate at the time of submission.

Subscribed and solemnly declared by the above named

at ……..... *(place)*

in the State of …….....

this …….. day (*date*) of …….. (*month*) 20……. (*year*)

Contact No : ……..(*h/p*)
…….(*office*)
Email address: ……...

)
)
)
)
)
)
)
)
)……..
(signature of declarant, official stamp with address)

Medicine name: _____

A. HEAD OF DEPARTMENT/UNIT	
COMMENT:	☐ SUPPORT ☐ NOT SUPPORT Signature: …… Name & Stamp: …… Date: ……
B. HEAD OF PHARMACY DEPARTMENT/ UNIT	
COMMENT:	☐ SUPPORT ☐ NOT SUPPORT Signature: …… Name & Stamp: …… Date: ……
C. HEAD OF INSTITUTION/FACILITY	
COMMENT:	☐ SUPPORT ☐ NOT SUPPORT Signature: …… Name & Stamp: …… Date: ……
D. CHAIRPERSON OF STATE DRUGS & THERAPEUTIC COMMITTEE / CHAIRPERSON OF DRUG WORKING COMMITTEE, MOH	
COMMENT:	☐ SUPPORT ☐ NOT SUPPORT Signature: …… Name & Stamp: …… Date: ……

A-FR-38/2

Appendix 9: Evidence Table (Effectiveness and Safety)

Bibliography/ Citations	
Study Design	
Level of Evidence	
Number of patients and patients' characteristics	
Intervention	
Comparison/ control	
Length of follow-up (if applicable)	
Outcome measures/ effect size	

A-FR-39/2

Appendix 10: Evidence Table (Economic Evaluations)

Title	
Abstract	
Introduction	
Background and objectives	
Methods	
Target population and subgroups	
Setting and location	
Study Perspective	
Comparators	
Time horizon	
Discount rate	
Choice of health outcomes	
Measurement of effectiveness	
Measurement and valuation of preference-based outcomes (if applicable)	
Estimating resources and costs	
Currency, price date, and conversion	
Choice of model	
Assumptions	

Analytical methods	
Results	
Study Parameters	
Incremental costs and outcomes	
Characterising uncertainty	
Characterising heterogeneity	
Discussion	
Study findings, limitations, generalisability, and current knowledge	
Other	
Source of funding	
Conflict of interest	

A-FR-16/3

Appendix 11A: Dossier D4 Form

Proposal to Delist Medicine(s)/ Indication(s) from the MOH Medicines Formulary

BACKGROUND

- This form is to be used for submission of a proposal to delist any medicine/indication(s) from the MOHMF. Any relevant supporting documents should be attached with the dossier.
- Applicant should provide detailed information about the medicine as required in the form below.

PROPOSAL TO DELIST:

MEDICINE ☐ SPECIFIC INDICATION ONLY ☐

***Tick in the appropriate box**

A. MEDICINE PARTICULARS			
1.	Generic Name [specify dosage form(s) & strength(s)/ concentration(s)]	*Provide full generic name as available in the MOHMF*	
2.	Malaysia Drug Code (MDC)	*Provide the MDC of the medicine as in the MOHMF*	
3.	Indication(s) to be Delisted	*Specify the indication in the MOHMF to be delisted or state all the indications if the medicine is to be delisted*	
4.	Prescriber Category		
5.	Is this Medicine or Indication used by other Discipline?	NO:	YES: *State the discipline(s)*
6.	Other Relevant Information (if any)		

B. RATIONALE FOR DELETION
Provide supporting documents (if any)

C. ALTERNATIVE MEDICINES FOR THE SAME/ SIMILAR INDICATION		
1	Other Medicine(s) for the Same Indication(s)	Generic name 1: …… MDC Code/ATC: ……
		Generic name 2: …… MDC Code/ATC: ……

D. OTHER REMARKS (IF ANY)

Medicine name: _____

E. HEAD OF DEPARTMENT/UNIT	
COMMENT:	☐ SUPPORT ☐ NOT SUPPORT Signature: …… Name & Stamp: …… Date: ……
F. HEAD OF PHARMACY DEPARTMENT/UNIT	
COMMENT:	☐ SUPPORT ☐ NOT SUPPORT Signature: …… Name & Stamp: …… Date: ……
G. HEAD OF INSTITUTION/FACILITY	
COMMENT:	☐ SUPPORT ☐ NOT SUPPORT Signature: …… Name & Stamp: …… Date: ……
H. CHAIRPERSON OF STATE DRUGS & THERAPEUTIC COMMITTEE / CHAIRPERSON OF DRUG WORKING COMMITTEE, MOH	
COMMENT:	☐ SUPPORT ☐ NOT SUPPORT Signature: …… Name & Stamp: …… Date: ……

FOR SECRETARIAT USE		
Dossier receipt date		**Comments:**
Dossier complete date		
Dossier reference no.		
Checked by		

A-FR-40/2

Appendix 11B: Applicant Statement of Declaration (Dossier D4)

(Institution letter head) Date:

Secretariat
MOH Medicines Formulary
Pharmacy Practice and Development Division
Ministry of Health Malaysia
Lot 36 Jalan Profesor Diraja Ungku Aziz
46200 Petaling Jaya, Selangor

STATEMENT OF DECLARATION

I, _____ (*name of applicant*) (NRIC No._____) do solemnly and sincerely declare the following:

1. That I am _____(*position in department/facility*) and am duly authorised to affirm this statement of declaration on behalf of the *department/facility*;
2. I do sincerely declare herewith that to my best knowledge and professional responsibility all the information submitted within this dossier is complete and accurate at the time of submission.

Subscribed and solemnly declared by the above named

at ……..... *(place)*

in the State of …….....

this …….. day (*date*) of …….. (*month*) 20……. (*year*)

Contact No : ……..(*h/p*)
…….(*office*)
Email address: ……..

)
)
)
)
)
)
)
)
)……...
(signature of declarant, official stamp with address)

A-FR-23/2

Appendix 12: MOHMF Information Update Request Form

MINISTRY OF HEALTH MEDICINES FORMULARY (MOHMF) INFORMATION UPDATE REQUEST FORM

A. APPLICANT DETAILS *Please tick (/) where applicable							
Applicant Name						Date	
*Type of facility		MOH		Product Registration Holder		Others: (please specify)	
Facility/ Company Name	(Example: Klinik Kesihatan XX, ABC Sdn. Bhd.)						
Telephone No.			Email				

B. MEDICINE INFORMATION			
Medicine name	(Example: Paracetamol 500mg tablet)		
*Please tick (/) where applicable			
	Generic name		Drug Interactions
	Indication		Adverse Drug Reactions
	Dose		Relisting
	Contraindications		Prescribing Restriction (Only for MOH facilities)
	Others (please specify):		
Details of Current Information:			

C. DETAILS OF AMENDMENT

D. HEAD OF DEPARTMENT/UNIT	
COMMENT:	☐ SUPPORT ☐ NOT SUPPORT Signature: …… Name & Stamp: …… Date: ……

FOR SECRETARIAT USE		
Date Received		*Comment*:
Reference No.		
Checked by		

Note: The completed form should be uploaded to http://tinyurl.com/cadangfukkm

FREQUENTLY ASKED QUESTIONS (FAQ)

GENERAL

1. **Can the PRH apply to list a product categorised as a medical device into the MOHMF since there are such products in the MOHMF?**
   Some medicines in the MOHMF classified as medical devices were considered drugs at the time of listing into the MOHMF. They are maintained in the MOHMF even though they have been reclassified as medical devices by the National Pharmaceutical Regulatory Agency (NPRA). Medical devices can still be used by MOH facilities despite not listed in the MOHMF.

2. **Has any prebiotics/probiotics ever been listed in the MOHMF? What is the procedure that has to be followed in order to get a supplement listed into the MOHMF?**
   No prebiotics or probiotics have ever been listed into the MOHMF. At the moment, there is no pathway for listing supplements into the MOHMF because the MOHMF comprises only medicines registered with the Drug Control Authority (DCA) with approved therapeutic claim(s). This means registered products for the general maintenance or promotion of health or wellbeing are not eligible for listing.

TYPES OF DOSSIER & FEES

1. **The PRH is registered in Malaysia, but can the PRH appoint its overseas office or a company located outside of Malaysia as the applicant-cum-liaison office for correspondences with the MOHMF Secretariat?**
   No, only the PRH in Malaysia is accepted as the liaison office for all correspondence with the MOHMF Secretariat. This is to ensure smooth communication and to prevent any undesirable circumstance related but not limited to matters regarding confidentiality of information throughout the entire dossier submission process.

2. **Can PRH submit dossier D4 (delisting)?**
   No. Only applicants from MOH facilities can submit proposal to delist medicine/ indication listed in the MOHMF.

3. **Can MOH pharmacists be the applicants for dossier D3 (amendment of prescriber category)?**
   Yes. Dossier for amending prescriber category can be submitted / applied by MOH healthcare professionals including pharmacists.

4. **Is there any procedure/guideline for listing of medicines into the MOH facilities' formulary?**
   For listing of medicines into the MOH facilities' formulary, facility may refer to "Tatacara Pengendalian Mesyuarat Jawatankuasa Ubat dan Terapeutik Di Fasiliti Kementerian Kesihatan Malaysia Edisi-2, 2024"

5. **Can a biosimilar product be listed in MOHMF, and if yes what type of dossier to be submitted?**
   Yes, biosimilar products can be listed into the MOHMF according to their International Non-proprietary Name (INN) and the listing process for any biologics will follow the same listing process.
   Example:
   a. Biologic (reference product) has been listed in the MOHMF – submission for listing biosimilar product is not required.
   b. If both reference and biosimilar products are not listed in the MOHMF – the listing of the biologic should be proposed through submission of Dossier D1 (new chemical entity).

LISTING PROCESS

1. **The LOA expires on 31 Jan 2022. Can the dossier be submitted by end of February without having to resubmit a new LOI?**
   Yes, you may submit the dossier. The secretariat will provide one-month grace period for the applicant to submit the dossier after the LOA voided.

2. **Do oncology medicines have to be listed in the MOH Systemic Protocol prior to listing in the MOHMF?**
   Inclusion into MOH Systemic protocol is not a pre-requisite for listing into the MOHMF.

3. **The medicine is not listed in the MOHMF and fulfills only some of the eligibility criteria. It is a new product and not reimbursed in any countries yet / in the process of listing in other countries. Can a dossier be submitted for listing into the MOHMF? This is to prevent delayed access of innovative medicines to Malaysian patients.**
   Applicant must provide justification with supporting document(s) (if any) when submitting the letter of intent for not fulfilling any of the eligibility criteria for dossier submission. Consideration may be given on a case-by-case basis. However, access is not hampered as the medicine is available to MOH patients via special approval provided that all the relevant criteria are met.

4. **Is the number of special approval applications one of the deciding factors or of any assistance for listing a medicine into the MOHMF?**
   The use of medicine under special approval may help in providing local data but not a definite criterion for listing a medicine into the MOHMF.

5. **The medicine was registered in January 2022 but launched in the Malaysian market and intended for listing into the MOHMF in October 2022. Hence, at the point of submitting the letter of intent, there is no official sales data yet. Does utilisation data during clinical trials / sampling programme considered as usage of the medicine?**
   First, the medicine is not yet eligible for listing because it does not fulfill the criterion "Medicine (new chemical entity) must be registered with the Drug Control Authority (DCA) in Malaysia for at least 12 months". The 12-month period starts from the date of DCA registration.
   Second, the purpose of this criterion is to provide sufficient information/ experience on the new drug in the local real-world setting. Hence, utilisation data during clinical trials may not fit this purpose. However, data from sampling programmes may be accepted.

6. **Does the definition of "listed in reimbursement list of other countries" also refer to having obtained regulatory approval status (example: marketing authorization approved in the UK but not recommended by NICE)?**
   No, it must be listed in reimbursement list of the country in any form.

7. **Can multiple indications for the same medicine be categorised as just one submission or dossier? Can any combination treatment or fixed dose combination (FDC) for similar indication as separate medicines listed in the MOHMF not require a separate dossier submission?**

   One medicine with multiple indications

   The evidence required for each indication will differ and the evaluation is as comprehensive as listing a new medicine. Therefore, separate dossiers are needed to facilitate the evaluation process (evaluation by different evaluators concurrently and communications with relevant experts which may be from different clinical disciplines based on indications) and avoid delays.

   However, applicant may contact the Secretariat for consultation if there is a reason to justify submission of a single dossier.

   One indication with combined medicines

   We take note of the suggestion given and may consider on a case-by-case basis as the suggestion may not be applicable in certain scenarios.

8. **What is the justification for the cooling off period after rejection?**

   A period of resubmission is needed to allow sufficient time for the applicant to review their dossier and to address reasons of rejection with new/updated supporting evidence.

9. **Who should sign the medicine price declaration for dossier submitted by MOH facilities?**

   The applicant should complete and sign the form based on current procurement price (APPL/ Central Contract) or price quoted by suppliers/companies (LP).

10. **Will the applicant be notified on the exact meeting date of panel meeting?**

    Panel meeting will be held 3 times in a year (Mac, July & November). The exact date for Panel Meeting is subject to change depending on the availability of the chairperson and/or committee members. The date of the Panel Meeting will not be informed to the applicant; only the month (as the date might change based on the availability of Panel Members).

11. **Is there any online tracking system for the applicant track progress of the submission?**

    At the moment, we do not have an automated tracking number system. However, applicant can enquire on the status of their applications by contacting the MOHMF Secretariat.

12. **What would be the process flow & timeline of review for deferred and rejected dossiers?**

    The applicant will be notified on the Panel's decision and reason(s) for rejection/deferment.
    Deferred dossiers do not require resubmission and will be tabled in the next panel meeting for decision. Refer Figure 1: Workflow of listing medicine into the MOHMF.

13. **What is the timeline for evaluation of a dossier? Is Budget Impact Analysis (BIA) screening process part of the evaluation timeline?**

    The maximum period for evaluation of a dossier is 90 working days. The BIA screening process is not part of the evaluation timeline. A dossier will only proceed for evaluation after it has successfully cleared the BIA screening process. The timeline for a dossier to clear the BIA screening process depends on the complexity of issues, extent of amendments required, and duration taken for obtaining feedback from relevant stakeholders. Applicant can follow up with the MOHMF Secretariat on the status of the dossier when needed.

14. **Is there any priority/ expedited review for listing into the MOHMF?**
    No, however, consideration may be given on a case-by-case basis such as medicine related to public health concerns and national policies.

15. **Can the applicant request to have access to revised BIA spreadsheet?**
    No. The revised BIA spreadsheet may contain confidential information that is not suitable to be shared with the applicant.

16. **What are the common resources to obtain local cost data for BIA?**
    Local cost data can be estimated from the Fee Act, local study and/or expert opinion.

17. **What is the ICER threshold being used to qualify a treatment as cost-effective?**
    Malaysia does not have an explicit ICER threshold to determine the cost-effectiveness of a new medicine relative to the existing treatment. Currently, in the MOHMF Panel decision, an implicit ICER threshold of 1 – 3 GDP per capita is being used with no restriction to use only 1 GDP/capita. This allows flexibility in decisions especially in cases where other factors are indicating a need for a medicine.

18. **According to Table 6 in the guideline, the recommended number of journal articles is 5 for Dossier D1 submission. What if there is limitation of clinical studies/ publications and this requirement could not be met?**
    The evidence requirement stated in the guideline is just a guide. The applicant can justify the number of evidence submitted if it did not fulfill the stated requirement. For example, absence of published economic evidence is a common scenario encountered. Therefore, it is acceptable if such evidence is not submitted.

19. **For dossier resubmission, does the minimum recommended number of journal articles still applies?**
    Yes, this minimum requirement applies for resubmission. However, if the reason of rejection is due to limited evidence/inferior efficacy or safety versus comparator, applicant needs to submit new evidence to support the application.

20. **Is clinical evidence (effectiveness and safety) required as supporting documents for submission of Dossier D3?**
    Though a medicine has been listed in the MOH Medicines Formulary based on established clinical benefits, the clinical evidence can change over time. Therefore, supporting clinical evidence is required to justify the submission of the D3 dossier if the reason for requesting change in prescriber category relates to the efficacy and safety of the medicine.

21. **For Dossier D3, how do we estimate the expected number of patients to be treated?**
    The estimation can be done in several ways and depends on the requested change in prescriber category. One approach would be based on the number of facilities likely to use the medicines multiplied by number of patients anticipated in each facility. For example, change in prescriber category for Drug X from A to A/KK can be estimated as follows:

    Number of primary care facilities with a Family Medicine Specialist (FMS) multiply by number of patients to be treated by each of the facility with FMS.

    The applicant may contact the Secretariat if any assistance or guidance is needed for this.

22. **If the applicant can revert and address the reason of rejection, can the same dossier be reviewed in the next meeting without having to resubmit a new dossier application?**
No, the applicant has to resubmit the dossier after the cooling period stated in Table 9: Resubmission cooling period.

23. **Why a dossier evaluation needs to be withheld or suspended if a change in DCA indication has not been informed to the MOHMF Secretariat?**
The key information required for the evaluation of any medicine for purpose of MOHMF listing is the DCA approved indication. The proposed indication for listing into the MOHMF must comply with the DCA approved indication and it defines the scope of the evaluation. There have been several cases where major changes to DCA indication occurred while the dossier was under evaluation and was not notified to the Secretariat. The Secretariat identified the changes in DCA indication during final stage of the evaluation process. This caused the evaluation to be no longer valid and a re-evaluation was required with new supporting documents (including new BIA model).

PROPOSAL TO AMEND INFORMATION OF MEDICINE LISTED IN MOHMF

1. **The existing indication listed in FUKKM is only for adults. Currently, the medicine has been approved for the use in children. Can PRH amend the indication by using the MOHMF Information Update Request Form?**
No, this amendment must go through dossier submission (D1 dossier: to add indication) because there is an expansion of use to a different target population.

2. **Can MOH facilities suggest to amend the prescriber category by using the MOHMF Information Update Request Form?**
Suggestion to amend prescriber category can only be applied via Dossier D3 submission by MOH facilities.

3. **Will multiple applications to amend prescribing restriction increase the chances of approval by the Panel?**
The Secretariat will process all applications received and present the proposal(s) to the Panel. However, multiple submissions do not guarantee the approval of such applications.

4. **Does the information update request by the MOH facilities need to be presented at the State Drug and Therapeutics Committee (DTC) before submitting to the Secretariat?**
No, the applicant can submit directly to the Secretariat using the form without needing cover letter or approval from the head of facility.