Guidelines on Submission of Dossier for Listing into the Ministry of Health Medicines Formulary

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Pharmaceutical Services Program
Ministry of Health Malaysia
Lot 36, Jalan Universiti,
46200 Petaling Jaya,
Selangor, Malaysia.

Tel : +603-78413200
Fax : +603-79682222
Website : www.pharmacy.gov.my
E-mail : sekretariatfukkm@moh.gov.my

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Advisors

Senior Director of Pharmaceutical Services
Ministry of Health Malaysia

Director of Pharmacy Practice and Development Division
Ministry of Health Malaysia

Deputy Director of Formulary Management Branch
Pharmacy Practice and Development Division,
Ministry of Health Malaysia

Contributors:
Deputy Directors, Pharmacy Practice and Development Division; Secretariat of MOH Medicines Formulary, Pharmacoeconomics and Evaluation Section, Formulary Management Branch, Pharmacy Practice and Development Division; Pharmaceutical Association of Malaysia (PhAMA); Malaysian Organisation of Pharmaceutical Industries (MOPI); Malaysian Association of Pharmaceutical Suppliers (MAPS); doctors, pharmacists and other organisations/individuals who had contributed their comments and suggestions in the development of this guideline.

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PART A: GENERAL INFORMATION

Introduction

The Ministry of Health Medicines Formulary (MOHMF) or *Formulari Ubat-ubatan Kementerian Kesihatan Malaysia* (FUKKM) serves as a reference for medicines used in public health institutions in Malaysia particularly those under the Ministry of Health (MOH).

This formulary provides an approach and administrative framework to encourage the rational and quality use of medicines in all MOH facilities in Malaysia. It contains list of medicines that have been approved by the Ministry of Health Medicines Formulary Review Panel (referred as the Panel henceforth). The Pharmacy Practice and Development Division (PPDD) acts as the Secretariat to the Panel and is responsible in processing the dossier submissions (referred as the Secretariat henceforth).

The online version of the MOHMF is accessible on the official portal of Pharmacy Services Program (PSP) at *www.pharmacy.gov.my*.

The main part of this guideline is written for applicants from pharmaceutical industries intending to apply for listing of their medicines into the MOHMF. The requirements are designed to promote uniformity of submissions and to minimize variability in the quality of the dossiers submitted. Where applicable, this guideline is also intended for use by applicants within the MOH.

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

Purpose

To guide applicants in preparing a standardized and complete dossier to support application for listing of medicines into the MOHMF.

Main Objective

To ensure medicines listed in the MOHMF are safe, of good quality, clinically effective, cost-effective and affordable.

Objectives

i) To assist applicants to present the values of their medicines.
ii) To ensure quality dossiers are submitted.
iii) To standardize the requirements of evidence in the dossier.
iv) To streamline process of listing medicines into the MOHMF.

Type of Dossier

This guideline is only applicable for the submission of the following type of dossier:

Type of Dossier	Details
D1	Proposal **to list new medicine(s)** into the MOH Medicines Formulary or a proposal **to list new indication(s)** for existing medicines in the MOH Medicines Formulary. • The number of medication/indication to be proposed is limited to one medication/indication for a dossier, either for proposal to list new medicine or to add indication.
D2	Proposal **to add or amend formulation/ dosage form/ strength** of medicines listed in the MOH Medicines Formulary.
D3	Proposal **to change category of prescriber** of medicines in the MOH Medicines Formulary.
D4	Proposal to add approved medicines in the MOH Medicines Formulary into institution's Medicines Formulary.
D5	Proposal to delist approved medicine(s)/ indication(s) from the MOH Medicines Formulary.

All proposals for listing must be made using appropriate forms as in Part B of this guideline.

Eligibility Criteria to Submit Dossier for Listing of Medicines into the MOH Medicines Formulary by Pharmaceutical Companies

All medicines intended to be applied for listing into the MOHMF must fulfill the following criteria at the time of submitting the Letter of Intent (LOI):

i) Medicine (new chemical entity)[1] must be registered with the Malaysia Drug Control Authority (DCA) for at least 12 months[2].

ii) Indication(s) must be approved by the Malaysia DCA.

iii) The medicine (and its indication(s) applied for listing) is listed in the reimbursement list/ national formulary in at least two countries.[3]

iv) Single chemical entity must be listed first in the MOHMF prior to the application of listing for the fixed dose combination of finished pharmaceutical product.
   - Applicant is required to provide valid justification if this criteria is not fulfilled (e.g. not marketed worldwide as a single ingredient product or not being used as single).
   - The listing of FDC without fulfilling the eligibility criteria will be considered on case-to-case basis.

[1] New chemical entity: A new product containing an active ingredient that has not been listed in the MOHMF.
[2] Only applicable to dossier D1 for listing of new medicine.
[3] Any countries. State the country referenced and provide supporting evidence.

v) Medicine must have been used for at least 6 months in Malaysia post DCA registration:
   - An updated Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER) must be made available upon submission of full dossier. Local safety report is preferred.
   - The usage after registration with DCA shall be supported with evidence of sale, including sample or trials.
     - The company may provide summary of sale which contains information on date for first sale, quantity for public and private sectors without stating the name of facilities involved (as long as you can show us that the drug has been used in Malaysia for 6 months after registration).

vi) Medicine must have therapeutic advantage supported by scientific evidence.
   - Comparative effectiveness and safety to the current standard practice evidences with head-to-head studies are highly preferred.

Listing of fixed dose combination product:

Fixed dose combination (FDC) product refers to a product that contains two or more active ingredients in a single dosage form.

The type of dossier to be submitted for listing of FDC product into the MOHMF shall be based on the following condition:

i) Dossier D1 (to list new medicine): if one of the active ingredients is not listed in the MOHMF. Applicant is required to provide strong justification to list FDC product without the listing of its single active ingredient into the formulary.
ii) Dossier D2 (to add formulation): if each single active ingredient is listed in the MOHMF, provided that the proposed indication for FDC product must be similar to indication(s) approved for its single active ingredient.

E.g.

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 formulation).

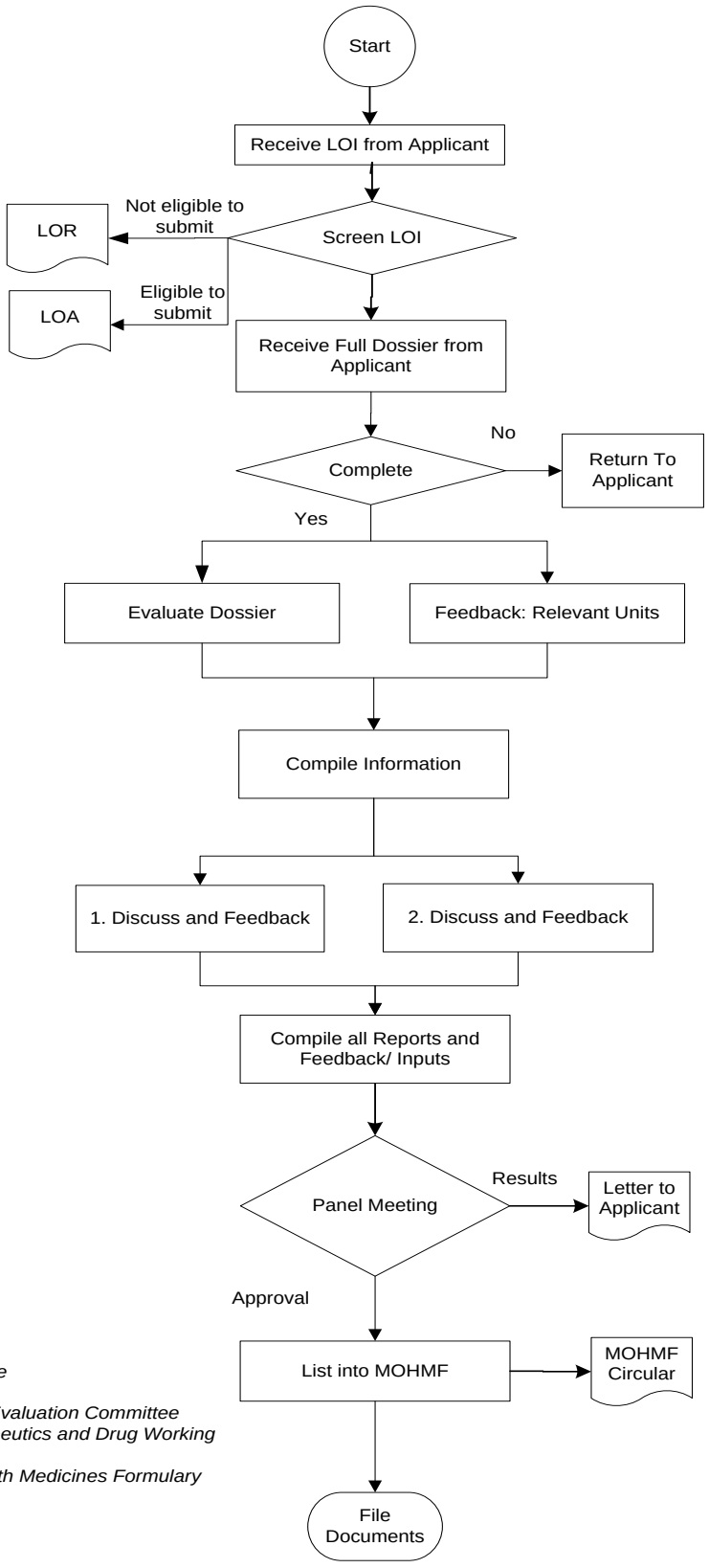
Applicants

The types of dossier and the corresponding eligible applicants:

Type of dossier	Applicant
D1	Pharmaceutical industries
D2	Pharmaceutical industries
D3	MOH[4] only
D4	MOH[3] only
D5	Pharmaceutical industries[5] or MOH[3]

[4] *The applicants from MOH include consultants/ specialists/ medical officers/ dentists/ pharmacists working in MOH institution or chairman of TDWC - where applicable.*
[5] *Relevant entity only.*

WORK FLOW OF LISTING MEDICINES INTO THE MOH MEDICINES FORMULARY



Abbreviations
LOI: Letter of Intent
LOA: Letter of Acceptance
LOR : Letter of Rejection
DE Committee: Dossier Evaluation Committee
TDW Committee : Therapeutics and Drug Working Committee
MOHMF: Ministry of Health Medicines Formulary

Elaboration on Process and Timing of Dossier Submission

Letter of Intent (LOI)

Prior to submission of a dossier (D1 or D2 only), LOI signed by an authorised company's representative needs to be submitted to the Secretariat to indicate the intent to submit a full dossier. The LOI should be written as per format suggested in **Appendix 1**. One (1) hardcopy of the LOI with supporting documents must be submitted to the Secretariat and the softcopy the documents should be emailed to **sekretariatfukkm@moh.gov.my**. At the time of submitting the LOI, the proposed medicine must fulfil eligibility criteria as listed in the **Appendix 1(a)**.

Letter of Acceptance (LOA)

The Secretariat will issue a LOA to the applicant within 5 working days of receiving the LOI. A complete dossier of the proposed medicine with all the supporting documents has to be submitted to the Secretariat within 6 months from the date of this acceptance letter.

This acceptance letter will be considered void if the Secretariat does not receive the dossier within the stipulated time. A new LOI can only be submitted at least 3 months after the previous LOA is voided.

Letter of Rejection (LOR)

Application that does not meet the listed eligibility criteria will not be permitted to proceed to full dossier submission. The Secretariat will issue a LOR to the applicant within 5 working days of receiving the LOI.

Submission of Full Dossier

Applicant may submit a complete dossier for consideration throughout the year. A copy of LOA must be attached together with the complete dossier. Evaluations will be performed and completed within 120 calendar days subject to a complete and satisfactory dossier is submitted to the Secretariat.

Confidentiality

All information provided to the Secretariat will be treated as confidential.

General Instructions for Dossier Preparation

A complete dossier with supporting documents and evidences for application to list medicine into the MOHMF or to propose for amendments to the existing list must be submitted to the Secretariat for evaluation.

When preparing documents for a dossier, the relevant template forms must be used and the guidance instructions detailed within the form should be complied.

The dossier form consists of four (4) sections:

Section	Particulars
Section 1	Medicine Information (Medicine Particulars, Clinical and Pharmacological Information and Costs)
Section 2	Rationale for Application and Comparators
Section 3	Clinical Evidences (Effectiveness and Safety)
Section 4	Economic Evidences (Economic Evaluations and/or Budget Impact Analysis)

Section 1
The guided instructions for each item required by the dossier are described in the right column of the template forms (see Part B of this document). These instructions provide details of expected content of each item. Information on product details must be in line with the information approved by DCA (e.g. the package insert).

Section 2, 3 and 4
Information and evidence to be provided in these sections can be in an unrestricted form. Applicant should exercise discretions on the quantity/ volume of evidence to be submitted. Evidence/ reviews should be comprehensive but concise, which are relevant to the application and should focus on the indication(s) proposed for listing.

The recommended number of journal articles required by the guideline is stated in the following table. Comparative effectiveness and safety to the current standard practice evidences with head-to-head studies are highly preferred:

Type of Dossier	*Recommended number of journal articles/ written evidence	Types of evidence
D1	**5**	Effectiveness and safety
	1	Economic evaluation and/or budget impact analysis
D2	**3**	Effectiveness and safety
	1	Economic evaluation
D3	**1**	Safety aspects must be included.
	1	Economic evaluation
D4	**As per institution's requirement**	As relevant
D5	**1**	As relevant

*Not applicable for resubmissions.

Additional materials that provide further weightage to the application and deemed necessary can be referenced. Full text of these additional materials should be provided as electronic copies instead of hardcopies. The applicant is responsible in providing any additional or specific journal article(s) when requested by the Secretariat.

The applicant is recommended to submit relevant references related to submission/ proposed indication(s) only.

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

Particular	**Format**	**Note(s)**
Dossier form	Microsoft Word	
Budget impact analysis/ Pharmacoeconomic models	Microsoft Excel	'Live' worksheet which can be modified
Other supporting documents	PDF or any readable format	To be provided as appendix (e.g. DCA approval letter; research papers, guidelines, etc.)
Language	English	Documents that are in other foreign language should be translated to English.
Font	Arial	
Font size	11	
Font colour	Black	Do not shade or highlight
Spacing	Single spacing	
Paper size	A4	
Page orientation	Portrait	
Printing	Double sided, black and white	
Indexing	Use numbers (e.g., Appendix 1, Appendix 2, and Appendix 3…)	
Arrangement of information in the dossier	Page 1 – File cover with name of medicine, type of dossier, contact person (with email and phone number); Page 2 – Dossier checklist; Page 3 – Table of content/ Index Table; Page 4 onwards – Main dossier	• Title of appendices must be clear and in line with submission requirements. • The four (4) sections of the dossier should be arranged clearly and marked with a suitable divider.
Filing of dossier	White colour, A4 size ring file	

Particular	Format	Note(s)
Divider	Coloured paper with index	Divider should be placed in front of each Section/ Appendix.
Sample of medicine	Only to be provided upon request by the Secretariat	

General Instructions for Dossier Submission

Three (3) duplicates of a complete dossier form and one (1) hardcopy of supporting documents (full paper for journals, DCA approval letter, package insert, related guideline, etc.) should be submitted.

Additionally, an electronic copy of the complete dossier form and its supporting documents in a USB drive/ CD (labelled with medicine names: generic and brand) should also be provided. The dossier form in the electronic copy should be prepared in Microsoft Word (editable format). Supporting documents can be in any suitable format (word, pdf, jpeg).

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.

All dossiers must be accompanied by a dossier checklist. A brief explanation should be provided for any missing information or document. Only complete applications will be accepted for processing. Incomplete or unsatisfactory applications will be returned to the applicant.

All submitted documents are deemed final upon submission of dossier unless there are new evidences/ information after the dossier submission. In this case, the applicant can contact the Secretariat to submit the additional documents.

For pharmaceutical companies, the complete dossier should be signed and submitted by an appointed pharmacist/ medical director or a corporate/ market access manager/ appointed officer (who will be the contact person for the dossier).

For MOH institutions, the dossier should be signed and submitted by eligible applicants. The relevant workflow process as in **Appendix 2** should be referred.

Withdrawal/ Amendment of Dossier

Withdrawal of dossier is allowed anytime. However, the dossier will be considered as rejected and cooling-off period for resubmission should be followed. (Note: Processing fee is not refundable). Any amendment by the applicant on the submitted dossier is not permitted after 14 days from the date of submission except which is requested by the Secretariat.

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

Resubmission

The decision made by The Panel is final and any disputes can be followed by a resubmission. Resubmission of dossier refers to an application that have been presented in previous Panel meetings but was rejected or an application that was previously withdrawn by the applicant.

Applicant is allowed to resubmit the same medicine for consideration provided that the reasons for rejection must be appropriately addressed. The cooling-off period for resubmission is also applicable to dossier that was previously withdrawn by the applicant.

Resubmission of dossier, which was previously rejected or withdrawn should comply to the following requirement:

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

* from the date of Panel Meeting.

Dossier Processing Fee

A non-refundable processing fee will be charged upon submission and resubmission of dossier as stated in the following table:

No.	Type of Dossier	Details of Application	Fee (RM)
1.	**Dossier 1 (D1)** i) Proposal to list new medicine(s) into the MOH Medicines Formulary or;	For application of new medicine.	*RM 5,000.00/ indication
	ii) Proposal to list new indication(s) for existing medicines in the formulary list.	• For application of new indication(s). • For application of new indication(s) which also involve addition of new formulation/ dosage form/ strength.	RM 3,000.00/ indication
2.	**Dossier 2 (D2)** Proposal to add or amend formulation/dosage form/ strength of medicines listed in the MOH Medicines Formulary.	For every application to add or amend formulation/ dosage form/ strength.	RM 2,000.00/ application

**one (1) indication per dossier.*

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

Contact Address for the MOHMF Secretariat

The complete LOI, dossier and other supporting documents should be submitted to:

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

The Secretariat can be reached by e-mail, sekretariatfukkm@moh.gov.my for further enquiry and assistance.

Pre-Submission Meeting

There are two (2) types of pre-submission meeting pertaining to submission of dossiers for listing of medicines into the MOHMF that can be requested by the pharmaceutical companies. The applicant is only eligible for one session of pre-submission meeting for each submission.

1) Standard Pre-Submission Meeting [after the issuance of Letter of Acceptance (LOA)]

Applicant may request for **Standard Pre-Submission Meeting** with the Secretariat for pending submissions within 6 months from the date of issuance of LOA. The meeting is intended to offer an opportunity for applicants to seek clarification on matters pertaining to submission requirements only.

2) Early Pre-Submission Meeting [before submission of Letter of Intent (LOI)]

Applicant may request for **Early Pre-Submission Meeting** with the Secretariat (before sending LOI) up to 12 months prior to submission of dossier with at least one of the following characteristics:

i) The drug is indicated for a relatively small patient population.
ii) Clinical data are limited to surrogate end points.
iii) The natural history of the disease is poorly characterized.
iv) There are limited numbers of clinical trials and they have small sample sizes.
v) Treatment has a higher cost in relative to appropriate comparators.
vi) The applicant has questions regarding the appropriate type of economic analysis to submit.

Applicant is advised to send supporting information for points aforementioned to the Secretariat. Decision to accept the request for an **Early Pre-Submission Meeting** will be made by the MOHMF Secretariat on a case-by-case basis.

Pre-Submission Meeting Request

To request for Pre-Submission Meeting, the applicant is required to complete a MOHMF Pre-submission Meeting Request Form as in **Appendix 3** and send it by e-mail to the Secretariat (sekretariatfukkm@moh.gov.my).

i) Standard pre-submission meeting: please fill in Section 1 and 2.
ii) Early pre-submission meeting: please fill in Section 1, 2 and 3.

The request form can be forwarded to the Secretariat at least seven (7) days prior to the proposed meeting date. A decision to accept the applicant's request for a pre-submission meeting will be made by the Secretariat on a case-to-case basis.

Pre-Submission Meeting Arrangement

The meeting will be scheduled for a maximum of one hour and the frequency is limited to one meeting per pending dossier submission. A maximum of three (3) representatives from the company are allowed in each session.

Post-Submission Meeting

The Secretariat reserves the right to call for a post-submission meeting (after submission of full dossier) if there are issues, which are unable to be resolved through correspondence by e-mail. Invitation for the meeting will be sent by e-mail to the respective applicant.

MOHMF Review Panel Meeting

MOHMF Review Panel is scheduled for 3 times a year as follows:

Meeting No.	Month
1	March
2	July
3	November

Nevertheless, the Panel Meeting dates are subject to change.

Presentation of Dossier in the Panel Meeting

The Secretariat reserves the right to determine the number of dossiers to be presented in each meeting taking into considerations the time allocated for the meeting. The selection of dossiers to be presented is on a first come – first serve basis. Applicants will be notified by e-mail within 30 days of the Panel Meeting.

Outcome of MOHMF Review Panel Meeting

The decision of MOHMF Review Panel Meeting on the presented dossier will be informed to the applicant within 15 working days from the date of the Panel Meeting, by e-mail and/ or official letter.

Decision of the Panel will be stated as accept, reject or defer.

PART B: GUIDELINES ON PREPARATION OF DOSSIER

DOSSIER D1

a) **To list new medicine(s) into the MOH Medicines Formulary, or**
b) **To list new indication(s) for existing medicines in the MOH Medicines Formulary.**

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 package insert.
- The latest DCA[6] approved package insert and DCA indication certificate 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 different line for each dosage form and strength/ concentration (if any).*
2.	Proprietary Name	*State the medicine's trade name as 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).*
6.	i) DCA Approved Indication(s)	*List all DCA approved indication(s) of the medicine.*
	ii) Proposed Indication(s) for the MOH Medicines Formulary (MOHMF)	*State indication(s) that will be proposed into the MOHMF.*
	iii) Proposed Restrictions of Use (if any)	*State any Prescribing Restriction(s) that are going to be imposed in prescribing the proposed medicine.* *(E.g. line of therapy, target population)*
7.	Declaration of products containing animal sources	*State the origins of the ingredients used in preparing the medicine.*

[6]*DCA: Drug Control Authority of Malaysia*

<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 other than Malay or English).
</td></tr>
</table>

<table>
<tr><th colspan="3">B. CLINICAL AND PHARMACOLOGICAL INFORMATION</th></tr>
<tr><td>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></td><td>a) Adult Dose</td><td></td></tr>
<tr><td></td><td>b) Paediatric Dose
c) (if applicable)</td><td></td></tr>
<tr><td></td><td>d) Dose in Renal Impairment</td><td></td></tr>
<tr><td></td><td>e) Dose in Liver Failure</td><td></td></tr>
<tr><td></td><td>f) 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 indications.</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 dosages, frequency and duration).</td></tr>
<tr><td>6.</td><td>Contraindications</td><td>State all contraindications. Provide references.</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. Provide references.* *State any changes that have been made since marketing authorization received from DCA.*
9.	Interactions (Medicine/ Food/ Disease)	*State the significant interaction(s) between medicine/ food/ disease. Provide references.*

C. DEVICE REQUIREMENT (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 (RM): ***(a)***	*State the nett price to MOH institutions, inclusive of all fees. Submit details as required in Medicine Price Declaration Form (**Appendix 4**).*
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 (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.*
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 of the application:

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

- *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.* • *If there is more than one proposed indication, state the comparators by each indication in separate tables.*
Existing medicine(s)/ comparator(s) in 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) of the same/ similar indication(s) or therapeutics class that are not listed in the MOHMF.*
Existing medicine(s)/ comparator(s) which have off-label use for the same/similar indication(s)	

SECTION 3: SUPPORTING CLINICAL EVIDENCE (EFFECTIVENESS AND SAFETY)

The decision for listing of new medicines into the MOHMF is based on evaluation of the comparative clinical safety and effectiveness of the medicines. It is important to provide comprehensive, relevant, clear, latest and unbiased evidences to support the application. Systematic and comprehensive literature search on the main search engines should be conducted and reported.

- Kindly submit studies, which are most relevant to the indications and the population applied. The most common sources of clinical evidence are:
  i) Meta-analyses or systematic reviews of randomized controlled trials (RCTs).
  ii) RCTs of active-controlled trials.
  iii) Placebo-controlled and uncontrolled trials can be included if active controlled trials are not available or relevant clinical benefits not demonstrated in active-controlled trials.
- Comparative effectiveness and safety to the current standard practice evidences with head-to-head studies are highly preferred.
- In the absence of valid RCTs, evidence from the highest available level of study design should be considered with reference to the limitations of the study design.
- Provide a detailed description of the systematic process used to obtain relevant evidence. This should include a description of the search strategy, inclusion and exclusion criteria applied and restrictions used in retrieving the studies (e.g. language, year).
- All evidences submitted should be summarized in an evidence table as shown in **Appendix 5**.
- Clinical evidence from trials conducted in Malaysia is preferred. Report briefly the result of clinical trial(s) or any research (published or unpublished) conducted in Malaysia if any.
- Provide the clinical progress reports on patients currently on the medicine including the summary of the relevant laboratory results/ indicators (if any).
- 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.
- Level of evidence for all studies and reviews should be classified based on categories as shown in **Appendix 6**.

SECTION 4: SUPPORTING ECONOMIC EVIDENCE

A. ECONOMIC EVALUATIONS

Evidence from economic evaluation is one of the elements considered in decision making for formulary listing. Therefore, applicant should attempt to submit full text article 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 7**.

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.

Conducting Local Pharmacoeconomic Research

Please refer to **Pharmacoeconomic Guideline for Malaysia** on details to conduct pharmacoeconomic research in the local setting. The guideline can be accessed online via www.pharmacy.gov.my. Local pharmacoeconomic research is not a compulsory requirement for submission of dossier D1.

B. BUDGET IMPACT ANALYSIS (BIA)

There is a growing recognition that a comprehensive economic assessment of a new health care intervention at the time of launch requires both a cost effectiveness analysis (CEA) and BIA. In the case of dossier D1 submission, BIA is a mandatory requirement.

The purpose of BIA is to estimate the financial consequences of adoption and diffusion of a new health-care intervention within a specific health-care 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.

Some points to be considered when performing BIA:

- 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.
- Malaysian data (e.g. 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.
- All projections should be for MOH only (e.g. not for the entire health care system).

- Full disclosure of methodology including calculation and uncertainty should be provided in a live spreadsheet of MS Excel format. Calculation should be accessible to the user and allow replication of analysis.
  - Abbreviations or legends used in the BIA model must be clearly defined.

The following six (6) main steps on reporting BIA recommended by the ISPOR Task Force can be used, which are:

i) Estimating the target population.
ii) Selecting a time horizon.
iii) Identifying current and projected treatment mix.
   - Treatment mix must include all relevant comparators, formulary or non-formulary medicines, which have same/similar indication as the proposed medicine.
iv) Estimating current and future drug costs.
v) Estimating changes in disease related costs.
vi) Estimating and presenting changes in annual budget impact. Both static and dynamic methods for estimating the budget and health impact of adding a new drug to a formulary.

A full write up (report) of BIA must be submitted together with MS Excel live worksheet.

For more information on principles of conducting a BIA, please refer:
Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget Impact Analysis – Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. Value in Health 2014; 17: 5 -14

APPLICANT STATEMENT OF DECLARATION

This section has to be signed by an appointed pharmacist/ medical doctor or a corporate/ market access manager/ appointed officer of the company. This person will also act as the contact person for this dossier.

Statement of declaration must be typed using company's/ facility's letterhead.

STATEMENT OF DECLARATION

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

1. That I am _____(*position in company*) and am duly authorized to affirm this statement of declaration on behalf of the company;
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 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.

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 stamp with address)

Checklist of Information to be Included in 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				
1.	Generic name of medicine (*including dosage form, strength, concentrations)*			
3.	Proprietary name			
4.	Registration holder			
5.	Manufacturer name and address			
6.	DCA registration number and date			
7.	DCA approved indication(s)			
8.	Proposed indication for the MOHMF			
9.	Proposed restriction(s) of use (if any)			
10.	Declaration of products containing animal sources			
11.	Most recent DCA indication certificate			
12.	DCA approved product information leaflet			
13.	Information on formulary/ reimbursements in other countries with supporting documents			
14.	Dosing and administration (including subpopulation doses)			
15.	Proposed course of treatment (duration) and repeats if any			
16.	Name of principal pharmacological/ therapeutic class			
17.	Concomitant therapies			

NO	PARTICULARS	TICK (✓)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
18.	Co-administered therapies for side-effects			
19.	Contraindications			
20.	Significant adverse effects			
21.	Warnings/ Precautions			
22.	Interactions (Medicine/ Food/ Disease)			
23.	Device requirement			
24.	Supply of device			
25.	Price per unit (SKU)			
26.	Number of dosage units per day or per cycle			
27.	Average duration of treatment in days or cycles per year			
28.	Total cost of medicine per patient per year			
29.	Additional cost per patient per year			
30.	Total annual cost per patient			
31.	Medicine Price Declaration Form (Appendix 4)			
Section 2: Rationale for Application and Comparators				
32.	Overview of disease			
33.	Rationale for listing application			
34.	Further elaboration on rationale for listing application			
35.	Existing medicines for same indication			
36.	Existing medicines in same therapeutic class			
37.	Non-pharmacological alternatives (if any)			
38.	Non-formulary comparators (if any)			
Section 3: Supporting Clinical Evidence (Effectiveness and Safety)				
39.	Summary of systematic search strategies for evidence			
40.	Supporting evidence for efficacy and safety (softcopy)			
41.	Evidence tables for each research paper			
42.	Clinical trial/ study reports conducted in Malaysia (if any)			

NO	PARTICULARS	TICK (✓)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
43.	Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)/Post Marketing Safety Report –Malaysia)			
Section 4: Supporting Economic Evidence				
44.	Economic evaluations/ reports (if any)			
45.	Evidence tables of PE studies			
46.	Budget impact analysis a) with softcopy in live MS excel format b) BIA Report			
Others				
47.	(Applicant Statement of Declaration) – Signature, stamp and contact details of the proposer			
48.	CD/ Softcopy of dossier (including research papers and economic models if any)			
49.	Sample of drug (one unit only with packaging/ box) if requested			
50.	List of references in Vancouver style			
51.	Relevant treatment guidelines (if available – softcopy only)			
52.	**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 of the fee.*			

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

NOTE:

- *Incomplete applications will not be processed.*
- *Please provide three (3) duplicates of the dossier form and one (1) hardcopy of supporting documents (DCA indication certificate, 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).*

FOR SECRETARIAT USE		
Receive date	:	**Comment :**
Registration number	:	
Checked by	:	

DOSSIER D2
To Add or Amend Formulation/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.* *List each formulation/ dosage form/ strength applied for on separate rows.*
		Existing medicine in MOHMF: *State all the formulation/ dosage form/ strength currently available in 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[7] 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. Latest DCA indication certificate must be submitted as reference*
		b) Indication(s) in MOHMF: *State current indication(s) listed in MOHMF.*
	ii) Proposed restriction of use (if any)	*State any Prescribing Restriction(s) that are going to be proposed in prescribing the medicine.* *(E.g. 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.*

[7] DCA – Drug Control Authority

B. CLINICAL AND PHARMACOLOGICAL INFORMATION		
8.	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)	
9.	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.*
10.	Concomitant Therapies (If any)	*If the medicine is to be used in combination with other therapies, state (if any) 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.*
11.	Co-administered Therapies to Manage Side-Effects	*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)*
12.	Contraindications	*State all contraindications when taking this medicine as approved by DCA. Provide references.*
13.	Significant Adverse Effects	*State the significant adverse reactions, references as approved by DCA and Post Marketing Surveillance reports available.*
14.	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 authorization received from DCA.*
15.	Interactions (Medicine/ Food/Disease)	*State the significant interaction(s) between 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 detail 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 the table below. • The estimated budget implications of introducing the new formulations/ forms/ strengths in MOH setting can also be included. • A cost comparison between new proposed medicine and existing medicine that is used for the same indication should be submitted by using **Appendix 8**.		
1.	Price Per Unit (RM): ***(a)***	*State the nett price to MOH institutions, inclusive of all fees. Submit details as required in Medicine Price Declaration Form (**Appendix 4**). Use separate form for each item (dosage form/ strength).*
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)*** Not limited to the MOH facilities (e.g. MOHE, MOD or private setting). Source of data must be reported.	*Additional cost per patient per year (e) [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.*
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 treatment.
- 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 application:

Provide justification for listing this formulation/ dosage form/ strength. (Include advantages and differences of the proposed formulation/ dosage form/ strength over the available therapies in the MOHMF).

State the proposed place of therapy for this new formulation/dosage form/strength in the disease treatment (e.g. first line, second line etc.)

State specific patient population that will benefit from the formulation/dosage form/strength (if any).

SECTION 3: SUPPORTING CLINICAL EVIDENCE (EFFECTIVENESS AND SAFETY)

- Provide a clear description of the systematic process used to obtain relevant evidence. This should include a description of search strategy, inclusion and exclusion criteria applied and restrictions used in retrieving studies (e.g. language, year).
- Evidence(s) on comparative effectiveness and safety to the current practice. Head-to-head studies are highly preferred.
- Information from all relevant studies should be summarised in evidence tables as shown in **Appendix 5**.
- Level of evidence for all studies and reviews should be categorized based on **Appendix 6**.
- Clinical evidence from trials conducted in Malaysia is preferred. Report briefly the result of clinical trial(s) or any research (published or unpublished) conducted in Malaysia if any.
- List of references should be written in Vancouver style.

SECTION 4: SUPPORTING ECONOMIC EVIDENCE

Economic Evaluations

Other related economic evaluations (if any) concerning the proposed new formulation/dosage forms/strengths of the medicines conducted abroad or locally that can support the application are welcomed. A summary of each study should be reported in an evidence table. Refer **Appendix 7** for the format to report economic evaluations. Full text of these documents (if any) can be included in the electronic copy of the dossier.

APPLICANT STATEMENT OF DECLARATION

This section has to be signed by an appointed pharmacist/ medical doctor or a corporate/ market access manager/ appointed officer of the company. This person will also act as the contact person for this dossier.

Statement of declaration must be typed using company's letterhead.

STATEMENT OF DECLARATION

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

1. That I am _____(*position in company*) and am duly authorized to affirm this statement of declaration on behalf of the company;
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 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.

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 stamp with address)

Checklist of Information to be Included in Dossier D2	
DOSSIER 2 (D2): PROPOSAL TO ADD OR AMEND FORMULATION / DOSAGE FORM / STRENGTH OF MEDICINES ALREADY 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				
1.	Generic name:			
2.	Proposed dosage form(s) & strength(s)/ concentration(s)			
3.	Currently available dosage form(s) & strength(s)/ concentration(s) in MOHMF			
4.	Proprietary name			
5.	Registration holder			
6.	Manufacturer			
7.	DCA Registration No.			
8.	Approved DCA indication(s)			
9.	Indication(s) in MOHMF			
10.	Proposed restriction of use (if any)			
11.	DCA approval letter/ Certificate of renewal (with full indication)			
12.	DCA indication certificate			
13.	DCA approved product information leaflet			
14.	Dosing and administration (including subpopulation doses)			
15.	Proposed course of treatment (duration) and repeats if any			
16.	Concomitant Therapies (If any)			
17.	Co-administered Therapies to Manage Side-Effects			
18.	Contraindications			
19.	Significant Adverse Effects			
20.	Warnings/ Precautions			
21.	Interactions (Medicine/ Food/ Disease)			
22.	Device requirement			
23.	Supply of device			

NO	PARTICULARS	TICK (✓)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
24.	Price per unit (SKU)			
25.	Number of dosage units per day or per cycle			
26.	Average duration of treatment in days or cycles per year			
27.	Total cost of medicine per patient per year			
28.	Additional cost per patient per year			
29.	Total annual cost per patient			
30.	Medicine Price Declaration Form (Appendix 4)			
31.	Cost comparison and financial implication of proposed drug vs. comparator/ existing medicine in MOHMF			
Section 2: Rationale for Application				
32.	Overview of disease and current management			
33.	Rationale for listing			
34.	Further elaboration on rationale for listing			
Section 3: Supporting Clinical Evidence (Effectiveness and Safety)				
35.	Summary of systematic search strategies for evidence			
36.	Evidence tables for each research paper			
37.	Supporting evidence for effectiveness and safety (softcopy only)			
38.	Clinical trial/ study reports conducted in Malaysia (if any)			
39.	Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)/ Post Marketing Safety Report –Malaysia)			
Section 4: Supporting Economic Evidence				
40.	Economic evaluations/ reports (if any)			
41.	Evidence tables of PE studies (if any)			
Others				
42.	(Applicant Statement of Declaration) – Signature, stamp and contact details of the proposer			

NO	PARTICULARS	TICK (✓)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
43.	CD/Softcopy of dossier (including research papers and economic models if any)			
44.	Sample of drug (one unit only with packaging/ box) if requested by Secretariat			
45.	List of references in Vancouver style			
46.	Relevant treatment guidelines (if available – softcopy only)			
47.	**Payment Information:** Bank draft/ money order/postal order made payable to '***KETUA SETIAUSAHA, KEMENTERIAN KESIHATAN MALAYSIA'.*** ( ) RM 2,000.00 [Proposal to add or amend formulation/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 of the fee.*			

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

Date :

NOTE:

- *Incomplete applications will not be processed.*
- *Please provide three (3) duplicates of the dossier form and one (1) hardcopy of supporting documents (DCA indication certificate, 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 notification in the dossier).*

FOR SECRETARIAT USE

Receive date	:	**Comment :**
Registration number	:	
Checked by	:	

DOSSIER D3
To Change Category of Prescriber of Medicines in the MOH Medicines Formulary

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)] MDC Code	*Provide full generic name as available in MOHMF. Provide MDC code for easy identification of the medicine.*	
2.	Indication(s) as in MOH Medicines Formulary	*State the corresponding indication(s) of the medicine proposed to be changed category of prescriber in MOHMF.*	
3.	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.*	
4.	Proposed restriction of use (if any):	*State any Prescribing Restriction(s) that are going to be imposed in prescribing the proposed medicine.* *(E.g. age, sex, conditions, severity of disease, stages of treatment etc.)*	
5.	Category of Prescriber	Existing category of prescriber in MOHMF:	
		Proposed category of prescriber:	
6.	Existing Medicines in MOHMF for the Proposed Category of Prescriber	*State alternatives in the MOHMF with the same indication and proposed category of prescriber.*	
7.	Is the Medicine a Replacement for Existing Alternative in MOHMF?	No	Yes: …… *(Suggest medicine(s) that can be replaced, please fill in Dossier D5)*

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.*
	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 (if any) 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 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. Provide references.*
6.	Significant Adverse Effects	*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 authorization received from DCA.*
8.	Interactions (Medicine/ Food/ Disease)	*State the significant interaction(s) between medicine/ food/ disease with complete reference details.*

C. SPECIAL DEVICE (if any)		
1.	Device Requirement	*State if the medicine need special device. If it is, 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 the table below.
- The estimated budget implications of introducing the new formulations/ forms/ strengths in MOH setting can also be included.
- A cost comparison between new proposed medicine and existing medicine that is used for the same indication should be submitted by using **Appendix 8**.

1.	Price Per Unit (RM): ***(a)***	*State the nett price to MOH institutions, inclusive of all fees. Submit details as required in Medicine Price Declaration Form (**Appendix 4**). Use separate form for each item (dosage form/ strength).*

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)*** Not limited to the MOH facilities (e.g. MOHE, MOD or private setting). Source of data must be reported.	*Additional cost per patient per year (e) [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.*
6.	Total Annual Cost Per Patient ***(f)***	***f =(d + e)***

SECTION 2: RATIONALE FOR APPLICATION

Select the main reason(s) of the proposal.		Has therapeutic advantage over an existing drug
		A cheaper alternative to an existing drug
		Improve compliance
		Safety issues
		Others (specify below):

Details on rationale of application

Provide justification to change category of prescriber.

State the proposed place of therapy for this change in the disease treatment (e.g. first line, second line etc.)

State specific patient population who will benefit from this change (if any).

SECTION 3: SUPPORTING CLINICAL EVIDENCE (EFFECTIVENESS AND SAFETY)

Change in medicine prescriber category (usually to less restricted category) would bring greater accessibility of medicines to patients. As a result, more patients will be exposed to the medicine. Thus, safety issues would be the main concern alongside effectiveness.

- The most relevant, clear, latest and unbiased evidence(s) such as for effectiveness and safety, should be submitted to support the application.
- Evidence(s) on comparative effectiveness and safety. Head-to-head study are highly preferred.
  - Please provide a clear description of the systematic process used to obtain relevant evidence. This should include a description of search strategy, inclusion and exclusion criteria applied and restrictions used in retrieving studies (e.g. language, year).
  - Studies should address aspects relevant to the application submitted on clinical safety, efficacy/effectiveness and/ or applicability of medicine. These evidences should be summarised in evidence tables as in **Appendix 5.**
  - Level of evidence for all studies and reviews should be classified based on categories as in **Appendix 6.**
  - Clinical evidence from trials conducted in Malaysia is preferred. Briefly report the result of clinical trial(s) or any research (published or unpublished) conducted in Malaysia if any.
  - Other relevant studies (published & unpublished) can be listed in full citation using Vancouver Style. Full text of these documents (if any) can be included in the electronic copy of the dossier.

SECTION 4: SUPPORTING ECONOMIC EVIDENCE

Economic Evaluations

Any other relevant economic evaluations (if any) conducted abroad or locally that can support the application are welcomed. A summary of each study should be reported in an evidence table. Refer **Appendix 7** for the format to report economic evaluations. Full text of these documents (if any) can be included in the electronic copy of the dossier.

APPLICANT STATEMENT OF DECLARATION

This section has to be completed by a pharmacist/ medical officer / specialist/ consultant working in MOH institution. The person will also act as the contact person for this dossier.

Statement of declaration must be typed using facility's letterhead.

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)*

A. SUPPORT BY HEAD OF DEPARTMENT
SUPPORT ☐ NOT SUPPORT ☐ Comment: …… …… Signature: ……. Date: ……. Name & Stamp: ……

Medicine name: ……

B. SUPPORT BY HEAD OF PHARMACY DEPARTMENT

SUPPORT ☐ NOT SUPPORT ☐

Comment:
……
……

Signature: …… Date: ……

Name & Stamp: ……

C. SUPPORT BY HEAD OF INSTITUTION

SUPPORT ☐ NOT SUPPORT ☐

Comment:
……
……

Signature: …… Date: ……

Name & Stamp: ……

D. SUPPORT BY CHAIRMAN OF STATE DRUGS & THERAPEUTIC COMMITTEE / CHAIRMAN OF THERAPEUTICS & DRUG WORKING COMMITTEE, MOH.
[where applicable]

SUPPORT ☐ NOT SUPPORT ☐

Comment:
……
……

Signature: …… Date: ……

Name & Stamp: ……

Extra notes

Applicant must ensure all the following section are completed:

- Application from HOSPITALS/HEALTH CLINICS – support is compulsory for A, B and C (D is optional).
- Application form Therapeutic Drug Working Committee – signature is compulsory for applicant and Chairman of Therapeutics & Drug Working Committee (D).

Checklist of Information to be Included in Dossier D3	
DOSSIER 3 (D3): TO CHANGE CATEGORY OF PRESCRIBER OF MEDICINES IN THE MINISTRY OF HEALTH 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				
1.	Generic name and MDC			
2.	Indication(s) as in MOHMF			
3.	Currently Available Brands, Product Registration Holder and Manufacturer			
4.	Proposed restriction of use (if any):			
5.	Existing category of prescriber in MOHMF			
6.	Existing Medicines/ Indication in MOHMF for the Proposed Category of Prescriber			
7.	Alternative to replace (if any)			
8.	The main reason(s) to change prescriber category			
9.	Details on rationale of application			
10.	DCA indication certificate			
11.	DCA approved product information leaflet			
12.	Dosing and administration (including subpopulation doses)			
13.	Course of treatment (duration) and repeats if any			
14.	Concomitant Therapies (If any)			
15.	Co-administered Therapies to Manage Side-Effects			
16.	Contraindications			
17.	Significant Adverse Effects			
18.	Warnings/ Precautions			
19.	Interactions (Medicine/ Food/ Disease)			
20.	Device requirement			
21.	Price per unit (SKU)			

NO	PARTICULARS	TICK (✓)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
22.	Number of dosage units per day or per cycle			
23.	Average duration of treatment in days or cycles per year			
24.	Total cost of medicine per patient per year			
25.	Additional cost per patient per year			
26.	Total annual cost per patient			
27.	Medicine Price Declaration Form (Appendix 4)			
28.	Cost comparison and financial implication of proposed drug vs. comparator/ existing medicine in MOHMF			
Section 2: Rationale for Application				
29.	Reason for the proposal			
30.	Details on rationale of application			
Section 3: Supporting Clinical Evidence (Effectiveness and Safety)				
31.	Summary of systematic search strategies for evidence			
32.	Evidence tables for each research paper			
33.	Supporting evidence for effectiveness and safety (softcopy)			
34.	Clinical trial/ study reports conducted in Malaysia (if any)			
35.	Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)/Post Marketing Safety Report –Malaysia)			
Section 4: Supporting Economic Evidence				
36.	Economic evaluations/ reports (if any)			
37.	Evidence tables of PE studies (if any)			
Others:				
38.	(Applicant Statement of Declaration) – Signature, stamp and contact details of the proposer			
39.	Signature and stamp from Head of Department; Head of Pharmacy Department, Head of Institution and Chairman of TDWC (where applicable)			

NO	PARTICULARS	TICK (✓)	Please provide reasons if the particulars are not submitted/ completed	For Secretariat Use
40.	CD/Softcopy of dossier (including research papers and economic models if any)			
41.	Sample of drug (one unit only with packaging/ box) if requested			
42.	List of references in Vancouver style			
43.	Relevant treatment guidelines (if any)			

Filled in by:

Date :

NOTE:

- *Incomplete applications will not be processed.*
- *Please provide three (3) duplicates of the dossier form and one (1) hardcopy of supporting documents (DCA indication certificate, journal articles, product information leaflet etc.). Any other supporting documents that are more than 20 pages shall be submitted in softcopy only (with notification in the dossier).*

FOR SECRETARIAT USE

Receive date	:		**Comment :**
Registration number	:		
Checked by	:		

DOSSIER D4

To Add Medicines/Indication Listed in the MOH Medicines Formulary into Institution's Medicines Formulary

Background:

A medicine/ indication is eligible for consideration to be added into the institution's Medicines Formulary only when it is listed/ approved in the MOHMF.

Dossier D4 is to be used by the applicant (consultant/ specialist/ medical officer/ pharmacist) for the purpose of listing into their institution's Medicines Formulary.

The form should be submitted to the Secretariat of the institution's Drug and Therapeutic Committee (DTC). The Secretariat will present a brief review of the application in the DTC meeting for approval.

The Secretariat should take into consideration the following matters:

- Current available alternatives in the institution's Medicines Formulary.
- Available budget for each discipline/ activity.
- Impact of adding the new medicine(s) to the overall medicine budget.
- Estimated number of patients to be treated with the new medicine.
- Training required in handling the new medicine (if any).

Pharmacist should monitor the utilization, costs and adverse effects of the newly approved medicine.

Approval for the said medicine for the Institution Medicines Formulary should be of the same prescriber category as the MOHMF or higher.

1. MEDICINE PARTICULARS *(to be filled by applicant)*		
1.	Generic name [specify dosage form(s) & strength(s)/ concentration(s)]	*Provide full generic name as available in MOHMF with the dosage form(s), strength(s) and concentration(s).*
2.	Indication(s) approved for MOH Medicines Formulary	*State all indication(s) to be proposed for listing in the institution's Medicines Formulary. The indications should be the indications approved.*
3.	Approved category of prescriber	*State the approved prescriber category as in the MOHMF.*
4.	Proprietary name	*State the medicine trade name as marketed in Malaysia*
5.	Dosing, frequency and duration of treatment	
6.	Existing medicine(s) with the same/ similar indication & annual procurement	Generic name 1: ……

	Add more lines if there are more than 3 alternatives currently available in the institution's Medicines Formulary	Year: …… RM ……	
		Generic name 2: …… Year: …… RM ……	
7.	The main reason(s) to list the product: *Please tick the main reason of the proposal.*		Has therapeutic advantage over an existing drug
			A cheaper alternative to an existing drug
			Improve compliance
			Others (please specify below):
8.	Is this a replacement for existing medication?	No	Yes: …….. *(medicine(s) that proposed to be deleted from the institution's formulary)*
9.	Other details on rationale of application:		

2. COSTS AND BUDGET IMPLICATION TO THE INSTITUTION		
1.	Estimated number of patients per year **(a)**	1. *(for therapeutic discipline 1)* 2. *(for therapeutic discipline 2)*
2.	Price per pack size (RM)	*State the SKU and the medicine costs per SKU unit agreed for MOHMF.*
3.	Dosing, frequency and duration of treatment	*Refer to sec. A*
4.	Total medicine cost per patient per year ***(b)***	
5.	Estimated total cost of medicine incurred per year ***(a x b)***	
6.	Available budget for the relevant discipline/activity	*The budget available for disciplines that are going to use the medicines should be stated* *1.* *2.*

3. APPLICANT'S STATEMENT OF DECLARATION

STATEMENT OF DECLARATION
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: …… Designation: …… Email Address: …… Official Stamp:

4. HEAD OF DEPARTMENT
SUPPORT ☐ NOT SUPPORT ☐ Comment: …… …… Signature: …… Date: …… Name & Stamp: ……

5. HEAD OF PHARMACY DEPARTMENT
SUPPORT ☐ NOT SUPPORT ☐ Comment: …… …… Signature: …… Date: …… Name & Stamp: ……

6. APPROVAL BY DRUGS & THERAPEUTICS COMMITTEE
APPROVE ☐ NOT APPROVE ☐ Comments: …… …… Signature (Chairperson): …… Meeting Date: …… Name & Stamp: ……

DOSSIER D5
To Delist Medicine(s)/ Indication from the MOH Medicines Formulary

BACKGROUND

- This form is to be used for submission of a proposal to delist any medicine/indication 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**

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

2. RATIONALE FOR DELETION
Include any supporting documents (if any)

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

4. OTHER REMARKS (IF ANY)

5. APPLICANT STATEMENT OF DECLARATION

This section has to be signed by an appointed pharmacist/ medical doctor or a corporate/ market access manager/ appointed officer of the company. This person will also act as the contact person for this dossier.

Statement of declaration must be typed using company's/ facility's letterhead.

STATEMENT OF DECLARATION

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

1. That I am _____(*position in company*) and am duly authorized to affirm this statement of declaration on behalf of the company;
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, company's stamp with address)

6. HEAD OF DEPARTMENT

SUPPORT ☐ NOT SUPPORT ☐

Comment:
……
……

Signature: ……

Date: ……

Name & Stamp: ……

7. HEAD OF PHARMACY DEPARTMENT
[for application from MOH Institution]

SUPPORT ☐ NOT SUPPORT ☐

Comment:
……
……

Signature: ……
Date: ……

Name & Stamp: ……

8. HEAD OF INSTITUTION
[for application from MOH Institution]

SUPPORT ☐ NOT SUPPORT ☐

Comment:
……
……

Signature: ……
Date: ……

Name & Stamp: ……

Medicine Name: ……

9. CHAIRMAN OF STATE DRUGS & THERAPEUTIC COMMITTEE / CHAIRMAN OF THERAPEUTICS &DRUG WORKING COMMITTEE, MOH. [where applicable]
SUPPORT ☐ NOT SUPPORT ☐ Comment: …… …… Signature: …… Date: …… Name & Stamp: ……

NOTE: Incomplete application will not be processed.

FOR SECRETARIAT USE		
Receive date	:	**Comment :**
Registration number	:	
Checked by	:	

APPENDICES

Appendix 1: Letter of Intent Format

Company/ Institution letter head Date:

Secretariat
MOH Medicines Formulary Review Panel
Pharmacy Practice and Development Division
Ministry of Health Malaysia
Lot 36 Jalan Universiti
46200 Petaling Jaya, Selangor

Intent to Submit Dossier for Listing of Medicine into the MOH Medicines Formulary

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

Generic Name:	
Strength(s):	
Dosage Form(s):	
Proprietary Name (Brand):	
Name & Address of Manufacturer:	
Name & Address of Registration Holder:	
DCA Registration Number:	MAL…
DCA Approved Indication(s):	
Proposed indication(s) for the MOH Medicines Formulary:	
Type of Dossier to be submitted:	D1 (to list new medicine/ to add indication(s))/D2/D3
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

2. I declare that the medicine has fulfilled all six (6) eligibility criteria listed in the Submission Guideline (as per Appendix 1a). I also 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.

Thank you.

Yours sincerely,

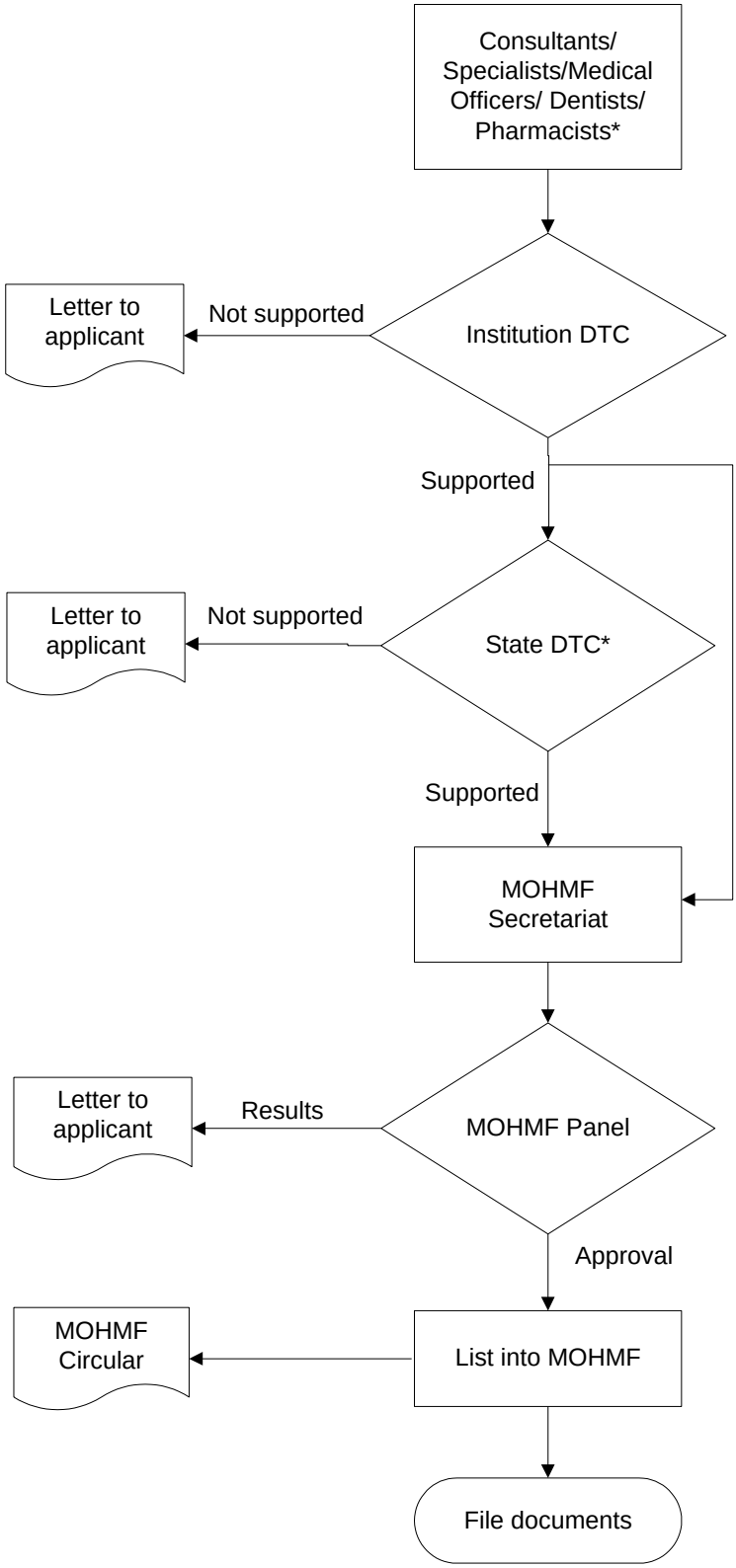
……
Name:
Designation:
Telephone No.:
Email Address:
*Please select one

Appendix 1(a): Six (6) 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.			
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*.			
4.	Single chemical entity must be listed first in the MOHMF before the application of listing for the fixed dose combination of finished pharmaceutical product. • Please provide valid justification if this criteria is not fulfilled.			
5.	Medicine must have been used for at least 6 months in Malaysia post DCA registration: • An updated Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER) must be made available. Local safety report is preferred. • The usage after registration shall be supported with sales report.			
6.	Medicine must have therapeutic advantage supported by scientific evidence. • Comparative effectiveness and safety to the current standard practice evidences with head-to-head studies are highly preferred.			

*Any countries. State the country referenced and provide supporting evidence (snapshot/ report of reimbursement that contain info – generic name, reimbursed price, indication and approval – in English/translated into English)

Appendix 2: Workflow of Application of Dossier D3 & D5 by MOH Institutions



Preparation of dossier D3 or D5 with supporting documents and checklist (3 copies).

Evaluation of dossier and consideration for support by institution's DTC

Evaluation of dossier and consideration for submission to MOHMF Secretariat.

Evaluation of dossier and preparation of report for MOHMF Panel Review Meeting.

Decision for listing into MOHMF

Abbreviations:
MOHMF: Ministry of Health Medicines Formulary
DTC: Drugs & Therapeutic Committee

Note:
* where applicable

Appendix 3: Ministry of Health Medicines Formulary (MOHMF) Pre-Submission Meeting Request Form

Type of Pre-Submission Meeting Requested (Please tick)

☐ **Standard Pre-Submission Meeting**

☐ **Early Pre-Submission Meeting**

Section 1 of this form is to be completed for both standard and early pre-submission meetings.

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 meeting*
Time	*Insert the proposed time of meeting*
Name of officers attending the Meeting (Company)	*Name the officers that are going to attend the meeting (maximum three)*
Questions to be asked/ Matters to be discussed	*State in details questions/ matters to be discussed in the meeting.*

*Section 3 of this form is to be completed **only** if an early pre-submission is being requested*

Section 3: Additional Information For Early Pre-Submission Meeting
Is the drug indicated for a relatively small patient population?
Response: ☐ Yes ☐ No **Supporting information:**
Are the clinical data limited to surrogate end points?
Response: ☐ Yes ☐ No **Supporting information:**
Is the natural history of the disease poorly characterized?
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 in 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 **Supporting information:**

Please use attachment if required

Contact Detail	
Contact Person	**Details**
Name	
HP/ Office Number	
E-mail	
Date	

Appendix 4: Medicines Price Declaration Form

MEDICINE PRICING DETAILS			**For Secretariat Use**
1.	Type of Dossier	(D1/D2/D3/D4)	
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 (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		

* 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:

1. 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 (e.g. 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.
2. Notification on the medicine price listed in MOH Medicines Formulary will be issued by Medicine Price Branch, Pharmacy Practice and Development Division.
3. Any offers for patient assisted programme should be explicitly declared and detailed.

Appendix 5: 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	

Appendix 6: Level of Evidence

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, e.g. case reports, case series
4	Expert opinion

(Source: Scottish Intercollegiate Guidelines Network)

Appendix 7: Evidence Table (Reporting 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	

Source: CHEERS (Consolidated Health Economic Evaluation Reporting Standards) Checklist. For further details on reporting economic evaluation, kindly refer to: http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp

Appendix 8: Cost Comparison and Financial Implication

(For Dossier D2 and D3)

COST COMPARISON [please *add more columns below if there is more than one comparator*]			
		New Drug	**Current Drug/Comparator**
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		
c	Average duration of treatment in days/cycle [*if continuous write '365'*)		
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 (*e.g. cost of monitoring, drug administration cost, cost of additional equipment required, etc*)	RM	RM
f	Total annual cost per patient ***f =(d+e**)***	RM	RM
g	Expected number of patients per year		
	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]			