

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



**Pharmaceutical Services Division
Ministry of Health Malaysia**

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

First Edition
October 2015

ALL RIGHTS RESERVED

No part of this publication may be reproduced, stored or transmitted in any form or by any means whether electronic, mechanical, photocopying, tape recording or others without prior written permission from the Senior Director of Pharmaceutical Services, Ministry of Health, Malaysia.

Pharmaceutical Services Division
Ministry of Health Malaysia
Lot 36, Jalan Universiti,
46350 Petaling Jaya,
Selangor, Malaysia.

Tel : 603-78413200
Fax : 603-79682222/79682268
Website : www.pharmacy.gov.my

ACKNOWLEDGEMENTS

The Pharmaceutical Services Division would like to express gratitude to all those who have involved directly or indirectly in preparing this Guidelines for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary.

Advisors

Dato' Eisah A. Rahman

Senior Director of Pharmaceutical Services Malaysia.

Madam Abida Haq Syed M. Haq

Director of Pharmacy Practice and Development,
Pharmaceutical Services Division, MOH.

Datin Dr. Faridah Aryani Md. Yusof

Deputy Director (Formulary & Pharmacoeconomics),
Pharmaceutical Services Division, MOH.

Contributors (in alphabetical order):

Aisha Adam, Angeline Tan Meng Wah, Anis Talib, Azuana Ramli, Azuwana Supian, Dazlinawati Daud, Haarathi a/p Chandriah, Hariana Haris, Hayati Alwani Yahaya, Lee Mei Wah, Leow Wooi Leong, Lim Yen Wei, Low Ee Vien, Masitah Husin, Munirah Jamal, Nazatul Syima Idrus, Noraini Saari, Norhamizah Mateni, Norul Aishah Mohd Yunus, Nur Sufiza Ahmad, Rokiah Isahak, Rosiah Harun, Rosilawati Ahmad, Rosliza Lajis, Rozita Mohamad, Sarahfarina Abd. Rahim, Siti Hajar Mahamad Dom, Tan Yoke Teng, Thamarai Chelvi Balachandran.

Members of Technical Drug Working Committee MOH, Malaysian Pharmaceutical Society, Pharmaceutical Association of Malaysia (PhAMA), Malaysian Organisation of Pharmaceutical Industries (MOPI), doctors, pharmacists and other organizations/individual whom had sent in comments and suggestions for development of this guideline.

External Reviewers

Professor Nathorn Chaiyakunapruk

School of Pharmacy,
Monash University Malaysia.

Assoc. Professor Dr. Asrul Akmal Shafie

Discipline of Social and Administrative Pharmacy,
School of Pharmaceutical Sciences,
Universiti Sains Malaysia.

TABLE OF CONTENTS

Part A: General Information	1
Introduction.....	1
Elaboration on Process and Timing of Dossier Submission	5
General Instructions for Dossier Submission	10
Part B (D1): Guidelines for Preparing Dossier D1	12
i) To List New Medicine(s) into the MOH Medicines Formulary	
ii) To List New Indication(s) for Existing Medicines in the MOH Medicines Formulary	
Part B (D2): Guidelines for Preparing Dossier D2	24
To Add or Amend Formulation/Dosage Form/Strength of Medicines Listed in the MOH Medicines Formulary	
Part B (D3): Guidelines for Preparing Dossier D3	33
To Change Category of Prescriber of Medicines in the MOH Medicines Formulary	
Part B (D4): Guidelines for Preparing Dossier D4	42
To Add Approved Medicines in the MOH Medicines Formulary into Institution's Medicines Formulary	
Part B (D5): Guidelines for Preparing Dossier D5	46
To Delist Approved Medicine(s)/ Indication(s) from the MOH Medicines Formulary	
Appendices	
Appendix 1: Letter of Intent Format.....	50
Appendix 1(a): Seven (7) Eligibility Criteria for Medicines Intended to be Applied for Listing into the MOH Medicines Formulary.....	51
Appendix 2: Supporting Document from Specialist/ Consultant.....	52
Appendix 3: Medicine Price Declaration Form	54
Appendix 4: Evidence Table (Efficacy/Effectiveness and Safety).....	55
Appendix 5: Level of Evidence.....	56
Appendix 6: Evidence Table (Reporting Economic Evaluations).....	57
Appendix 7: Workflow of Application of Dossier D3 & D5 by MOH Institutions	59

PART A: GENERAL INFORMATION

Introduction

The Ministry of Health Medicines Formulary (MOHMF) or *Formulari Ubat Kementerian Kesihatan Malaysia (FUKKM)* serves as a reference for medicines used in public health institutions in Malaysia particularly in 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 (which will be referred as The Panel in this document). The Pharmaceutical Services Division (PSD) acts as The Secretariat to The Panel and is responsible in processing the dossier submissions (which will be referred as The Secretariat in this document).

The online version of the MOHMF can be found on the PSD's website 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 products 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 Ministry of Health (MOH).

This guideline will provide practical information on how to prepare a complete dossier for this purpose. 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. It should be noted however that a complete application does not guarantee listing of a medicine into the MOHMF.

Purpose

To guide applicants in producing a standardized and complete dossiers to support applications for listing medicines into the MOHMF.

Main Objective

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

Objectives

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

Type of submissions

This guideline is only applicable for the following type of submissions:

- i) Dossier 1 (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.
- ii) Dossier 2 (D2):**
Proposal to add or amend formulation/ dosage form/ strength of medicines listed in the MOH MEDICINES FORMULARY.
- iii) Dossier 3 (D3):**
Proposal to change category of prescriber of medicines in the MOH MEDICINES FORMULARY.
- iv) Dossier 4 (D4):**
Proposal to add approved medicines in the MOH MEDICINES FORMULARY into institution's¹ Medicines Formulary.
- v) Dossier 5 (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.

Applicants

Table 1: The types of dossier and the corresponding eligible applicants:

Type of dossier	Applicant
D1	Pharmaceutical industries
D2	Pharmaceutical industries
D3	MOH ² only
D4	MOH ² only
D5	Pharmaceutical industries or MOH ²

¹ include hospitals, health clinics, special medical institution (for example National Cancer Institute, Institute of Respiratory Medicines).

² The applicants from MOH include consultants/ specialists/ medical officers/ dentists/ pharmacists working in MOH institution or chairman of Therapeutics and Drugs Working Committee (TDWC) - where applicable.

Resubmission

The decision made by The Panel is final and any disputes can be followed by a resubmission.

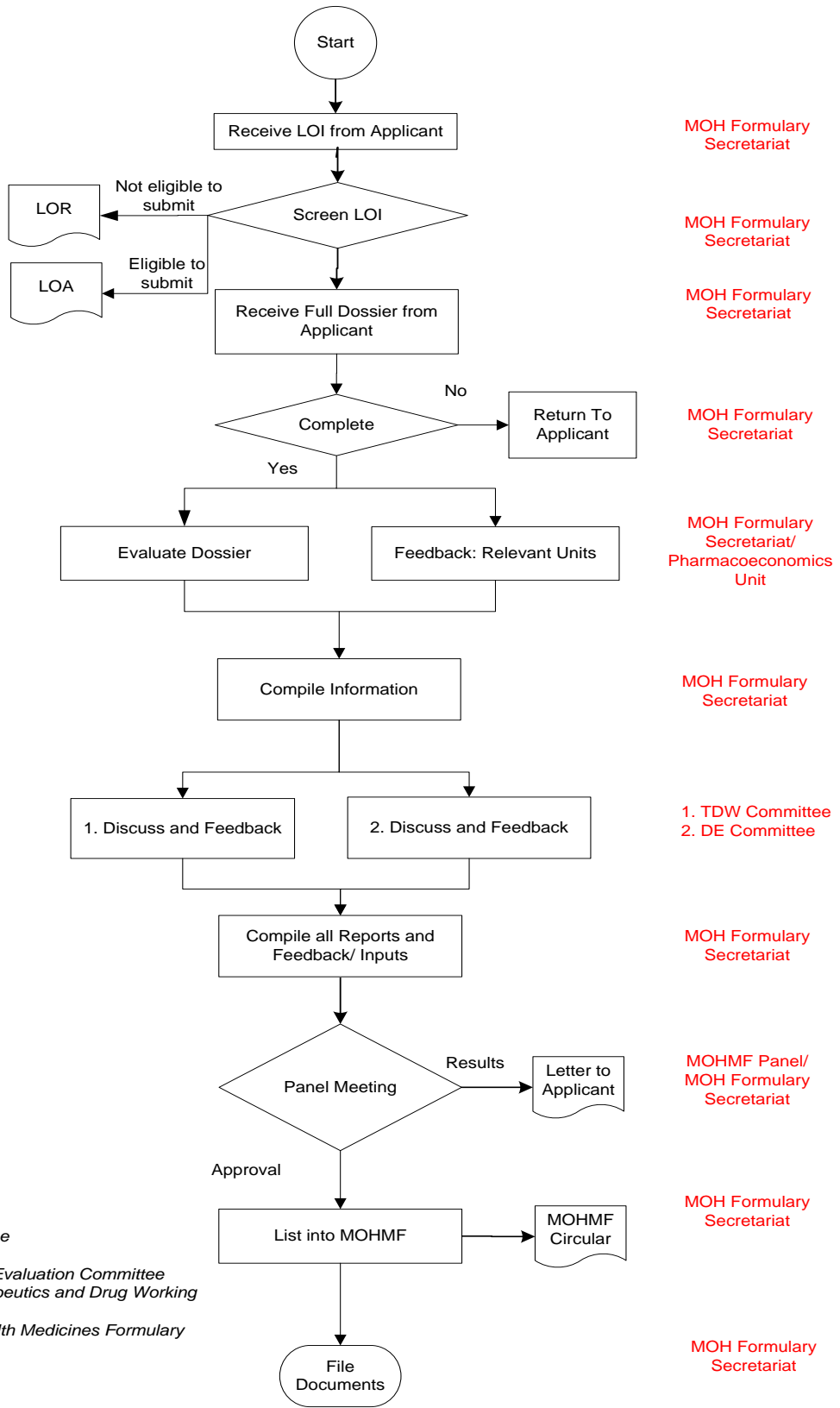
Resubmissions refer to applications that have been presented in previous Panel meetings but were rejected.

Applicant can resubmit the same medicine for consideration for listing after at least 6 months from the date of rejection and reasons for rejection (if any) have been addressed with any of the following conditions fulfilled:

- i) Significant new clinical information supporting improved efficacy and safety has emerged. Published reports on the relevant randomised control trials (RCTs) or case-control or cohort studies (if RCTs not available) should be submitted.
- ii) Significant cost reduction is offered that affects the cost-effectiveness of the medicine. A new economic evaluation should be submitted.

If a resubmission is rejected the subsequent resubmission can only be done at least 12 months from the date of rejection and the conditions above have been fulfilled.

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 official needs to be submitted to the Secretariat to indicate the intent to submit the full dossier. At the time of submitting the LOI, the proposed medicine must fulfill the eligibility criteria as listed below. The LOI should be written as per format suggested in **Appendix 1**.

Supporting document from two consultants or specialists in the related therapeutic field working in different MOH institutions³ should be attached as per format in **Appendix 2**. The purpose of these supporting documents is to confirm there is need for the medicines to be listed in the MOHMF.

Letter of Acceptance (LOA)

The Secretariat will issue a LOA to the applicant within 5 working days of receiving the LOI. The full 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.

Letter of Rejection (LOR)

Application that does not meet the criteria listed 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 LOI.

Eligibility Criteria to Submit Dossier for Listing 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 LOI:

- i. Medicines must be registered with the Drug Control Authority (DCA) in Malaysia for at least 12 months.
- ii. Indication(s) must be approved by the DCA in Malaysia.
- iii. The medicine (and its indication(s) applied for listing) is listed in the reimbursement list / national formulary in at least two countries.⁴
- iv. Single chemical entity must be listed first in the MOHMF before the application of listing for the fixed dose combination of finished pharmaceutical product.

³ include hospitals, health clinics, special medical institution (for example National Cancer Institute, Institute of Respiratory Medicines)

⁴ any countries. State the country referenced and provide supporting evidence.

- v. Medicines must have been used for at least 12 months in Malaysia post DCA registration. An updated Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER) must be made available.
- vi. Medicines must have therapeutic advantage supported by scientific evidence.
- vii. Each application must be supported by two consultants/ specialists in the related therapeutic field working in different MOH institutions in Malaysia.

Dossier Submission Cut-off dates

In order to provide sufficient time for complete evaluation of the dossier, a minimum period of 14 WEEKS from the date of submission of full dossier is required for presentation in The Panel Meeting. All complete dossiers together with a copy of the LOA should be submitted to The Secretariat. Applicant must follow the cut-off dates listed below for the dossier to be presented in the respective meetings.

Table 2: Panel Meeting Dates and Submission Cut-off Dates

Meeting No	Planned Panel Meeting Date	Submission Cut-off Date
1	March	1 st December
2	July	1 st April
3	November	1 st August

It should be noted that The Panel Meeting dates are subject to changes. The Secretariat reserves the right to determine the number of dossiers to be considered in each meeting taking into considerations the 14 WEEKS period for evaluation as well as the total number of dossiers that can be managed in one Panel Meeting.

Confidentiality

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

General Instruction for Dossier Preparation

To apply for listing of medicines (including amendments to the present list) in the MOHMF, a complete dossier containing the relevant information and evidence on the proposed medicines need to be submitted to The Secretariat of The Panel Meeting at the PSD, MOH.

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

Type of submissions

This guideline is only applicable for the following type of submissions:

- i) Dossier 1 (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.
- ii) Dossier 2 (D2):**
Proposal to add or amend formulation/ dosage form/ strength of medicines listed in the MOH MEDICINES FORMULARY.
- iii) Dossier 3 (D3):**
Proposal to change category of prescriber of medicines in the MOH MEDICINES FORMULARY.
- iv) Dossier 4 (D4):**
Proposal to add approved medicines in the MOH MEDICINES FORMULARY into institution's Medicines Formulary.
- v) Dossier 5 (D5):**
Proposal to delist approved medicine(s)/indications(s) from the MOH MEDICINES FORMULARY.

The template form consists of four (4) sections:

Section 1: Medicine Information (Medicine Particulars, Clinical and Pharmacological Information and Costs)

Section 2: Rationale for Application and Comparators

Section 3: Clinical Evidence (efficacy/ effectiveness and safety)

Section 4: Economic Evidence (Economic evaluations and Budget Impact Analysis)

In Section 1 (Medicine Information) of the form, the guidance instructions for each item required by the dossier are described in the right column of the template forms. These instructions detail the expected content of each item. Information on product details must be in line with the information approved by DCA (for example the package insert)

For Section 2, 3 and 4 where information and evidence can be in a more unrestricted form, applicant should exercise discretions in the quantity/ volume of evidence to be submitted. Evidence/ reviews should be comprehensive but concise and relevant to the application. The evidence should focus on the indication(s) proposed for listing.

The recommended number of journal articles required by the guideline is stated in the Table 3 below. Additional materials that provide further weightage to the application and deemed necessary can be referenced. Full text of these additional materials should not be included in the dossier file but can be provided in the electronic copy. The applicant is responsible in providing any additional or specific journal article(s) when requested by the Secretariat.

Table 3: Summary on the number of journal articles required for each type of dossier.

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

*Not applicable for resubmissions

To ensure uniformity of dossiers and to facilitate the evaluation process, dossiers should be prepared following the general guidance as follows:

1. The main document (the form) should be prepared in Microsoft Word. Pharmacoeconomic models/ decision trees template should be in a non-proprietary format preferably in Microsoft Excel.
2. All information presented (including appendices and any supporting documents) should be in English.
3. Use *Arial* font.
4. Font size – 11
5. Font color – Black. Do not shade or highlight.
6. Line spacing should be *single*
7. Double-sided printing
8. Page orientation – potrait.
9. Indexing – Number format should be in 1, 2, 3 form (e.g. Appendix 1, Appendix 2, Appendix 3...)
10. Supporting documents should be included in appendices, for example DCA approval letter, research papers, evidence tables and other relevant/ additional documents.
11. The medicine names and applicant details should be on the first page of the document.

12. Dossier checklist should be on the second page (use the template provided).
13. Table of Contents/ Index Table should be placed on the third page. Title of Appendices must be clear and follow submission requirements.
14. Any references quoted throughout the dossier should be properly referenced and numbered in the order of appearance in the text. Reference list should be provided in Vancouver style at the end of the dossier.
15. All documents of the dossier should be compiled in a SINGLE ring file, for A4 size paper. The 3 parts of the dossier should be arranged clearly marked with a suitable divider.
16. Divider – Use colored paper with index. A divider should be placed in front of each Appendix.
17. Sample medicine should be provided upon request by The Secretariat.

General Instructions for Dossier Submission

Three (3) duplicates of a complete dossier and all the supporting documents should be submitted. Additionally, an electronic copy of the complete dossier and its supporting documents in a CD form (labelled with medicine names: generic and brand) should also be submitted. The dossier form in the electronic copy should be provided in Microsoft Word (in an editable format). Supporting documents can be in any suitable format (word, pdf, jpeg). Any additional documents that are too voluminous to be included in the hard copy can be included 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 given for any missing information or document. Only complete applications shall be accepted for processing. Incomplete or unsatisfactory applications will be returned to the applicant. Completed dossier should be submitted to The Secretariat before the cut-off date to be eligible for consideration in the respective meeting.

A non-refundable submission fee will be charged with every submission and resubmission as stated in the Table 4 below:

Table 4: Processing Fees for Application of Dossier

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
	ii) Proposal to list new indication(s) for existing medicines in the formulary list.	<ul style="list-style-type: none">• 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
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

**Approval by General Secretary, Ministry of Health.*

For pharmaceutical companies, the complete dossier should be signed and submitted by an appointed pharmacist/ medical director or a corporate/ market access manager.

For MOH institutions, the dossier should be signed and submitted by eligible applicants. The relevant workflow process as in **Appendix 7** should be referred.

The complete dossier should be submitted to:

Secretariat
Ministry of Health Medicines Formulary Review Panel
Pharmaceutical Services Division
Ministry of Health Malaysia
Lot 36 Jalan Universiti
46350 Petaling Jaya, Selangor.

PART B (D1): GUIDELINES FOR PREPARING DOSSIER D1

- i) To list new medicine(s) into the MOH Medicines Formulary
- ii) To list new indication(s) for existing medicines in the MOH Medicines Formulary

1. MEDICINE INFORMATION

Instructions

- Applicant should provide detailed information about the medicine as required in the form below.
- The information should be obtained from official reliable sources for example medicine monograph or package insert.
- The latest DCA⁵ approved package insert must be attached.
- 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)]	<i>Provide full generic name of the medicine. Use different line for each dosage form and strength/ concentration (if any).</i>
2	Proprietary Name	<i>State the medicine brand name as marketed in Malaysia.</i>
3	Registration Holder	<i>State the company name and address.</i>
4	Manufacturer	<i>State the company name and address.</i>
5	DCA Registration No.	<i>State DCA Registration number and date of registration of the medicine. (Attach the DCA Approval Letter/ Latest certificate of renewal with full indication).</i>
6	i) DCA Approved Indication(s)	<i>List all DCA approved indication(s) of the medicine.</i>
	ii) Proposed Indication(s) for the MOH Medicines Formulary (MOHMF)	<i>State the indication(s) that are to be proposed to be listed in MOHMF.</i>
	iii) Restrictions of Use (if any)	<i>State any 'restrictions of use' that are going to be imposed in prescribing the medicine for example for group of patients (age, sex, conditions etc), severity of disease, stages of treatment etc.</i>

⁵ DCA: Drug Control Authority of Malaysia

7	Declaration of products containing animal sources	<i>State the origins of the ingredients used in preparing the medicine.</i>																																																				
8	Formulary/ Reimbursement in other countries	<table border="1"> <thead> <tr> <th>Country</th> <th>Status of listing</th> <th>Year listed</th> <th>Approved Indication(s)</th> </tr> </thead> <tbody> <tr><td>Australia</td><td></td><td></td><td></td></tr> <tr><td>Canada</td><td></td><td></td><td></td></tr> <tr><td>France</td><td></td><td></td><td></td></tr> <tr><td>Japan</td><td></td><td></td><td></td></tr> <tr><td>UK</td><td></td><td></td><td></td></tr> <tr><td>Switzerland</td><td></td><td></td><td></td></tr> <tr><td>Sweden</td><td></td><td></td><td></td></tr> <tr><td>Thailand</td><td></td><td></td><td></td></tr> <tr><td>Taiwan</td><td></td><td></td><td></td></tr> <tr><td>Indonesia</td><td></td><td></td><td></td></tr> <tr><td>Others</td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td></tr> </tbody> </table> <p><i>State whether the medicine is listed in any of the countries above. Fill in the year the medicine was listed and state the approved indications.</i></p> <p><i>Attach supporting evidence.</i></p>	Country	Status of listing	Year listed	Approved Indication(s)	Australia				Canada				France				Japan				UK				Switzerland				Sweden				Thailand				Taiwan				Indonesia				Others							
Country	Status of listing	Year listed	Approved Indication(s)																																																			
Australia																																																						
Canada																																																						
France																																																						
Japan																																																						
UK																																																						
Switzerland																																																						
Sweden																																																						
Thailand																																																						
Taiwan																																																						
Indonesia																																																						
Others																																																						

B. CLINICAL AND PHARMACOLOGICAL INFORMATION		
1	Dosing and Administration (Dose, Frequency, Route of administration)	<i>State the dose frequency and route of administration for the medicine in all population groups for each indication applied.</i>
	1a. Adult Dose	
	1b. Paediatric Dose (if applicable)	
	1c. Dose in Renal Impairment	
	1d. Dose in Liver Failure	
	1e. Others (if any)	

2	Proposed course of treatment (Duration) and repeats if any	<i>State the recommended duration of treatment and treatment cycle (if any). State 'life-long' if the medicine will be used continuously by the patient.</i>
3	Name of principal pharmacological/ therapeutic class	<i>State the principal pharmacological/therapeutic class of the medicine and its Anatomical Therapeutic Classification (ATC).</i>
4	Concomitant Therapies	<i>If the medicine is to be used in combination with other therapies, state (if any) the concomitant therapies with the dosage, frequency and duration. State all the concomitant therapies for each proposed indications (if any).</i>
5	Co-administered Therapies to manage side-effects	<i>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).</i>
6	Contraindications	<i>State all contraindications. Provide references.</i>
7	Adverse Reactions	<i>State all adverse reactions. Provide Periodic Safety Update Report (PSUR) or Periodic Benefit-Risk Evaluation Report (PBRER).</i>
8	Warnings / Precautions	<i>State all warnings and precautions. Provide references. State any changes have been made since marketing authorization received from DCA.</i>
9	Interactions (Medicine/ Food/Disease)	<i>State the significant interaction(s) between medicine/ food/ disease. Provide references.</i>

C. SPECIAL DEVICE (if any)

1	Device Requirement	<i>State if the medicine needs special device. If yes, please provide detailed information.</i>
---	--------------------	---

2	Supply of Device	<i>State the supply mechanism of the above said device (e.g. : Free of charge, to be purchased separately)</i>
D. MEDICINE AND RELATED TREATMENT COSTS		
1	Price Per Unit (RM): (a)	<i>State the nett price to MOH institutions, inclusive of all fees. Submit details as required in Medicine Price Declaration Form (Appendix 3). Use separate form for each item (dosage form/ strength).</i>
2	Number of dosage units administered per day or per cycle (b)	<i>State the number (or average number) of dosage units administered per day or per cycle.</i>
3	Average duration of treatment in days or cycles per year (c)	<i>State the average duration of treatment in days or number of cycles per year. If the treatment is continuous for 1 year, use 365 days. If the product is an antibiotic, state number of days per treatment.</i>
4	Total medicine cost per patient per year (d) $d = a \times b \times c$	<i>This can be calculated by multiplying a, b and c</i>
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.	<i>List all potential additional costs. Calculate potential additional costs per patient per year. This may include cost of monitoring, drug administration cost, cost of additional equipment required, costs to control adverse effects etc.</i> <i>If no published data is available, estimates can be used. However, estimates need to be justified.</i>
6	Total annual cost per patient (f)	$f = (d + e)$

2. RATIONALE FOR APPLICATION AND COMPARATORS

2a. OVERVIEW OF THE DISEASE AND CURRENT MANAGEMENT

- Provide an overview of the disease and the patient population that the product is targeted for.
- Provide data on disease prevalence and epidemiology in Malaysia.
- Global epidemiology data may also be included.
- Provide brief overview on the current disease management.
- Other relevant information can also be included.

2b. 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 (specify below):
Details on rationale of the application:	
<i>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.</i>	
<i>State the place of therapy for this new medicine in the disease treatment (e.g. first line, second line etc.)</i>	
<i>State the specific patient population that will benefit from this medicine (if any).</i>	

2c. EXISTING TREATMENT/ MEDICINE(S)

Existing Treatment/ Medicine(s) for the same/similar indication(s) in MOH MEDICINES FORMULARY <i>[specify strength & dosage form]</i>	
Existing medicine(s)/ comparator(s) for the same/similar indication(s)	<ul style="list-style-type: none">• <i>List all the existing medicine(s) in MOHMF with the same/similar indication(s). Provide medicine names, strengths and dosage forms.</i>• <i>If there are more than one proposed indication, state the comparators by each indication in separate tables.</i>
Other alternatives (non-pharmacological)	<i>List all non-pharmacological therapies which can be used for the same indication (if any).</i>
Other medicine(s) with the same/similar indication not listed in the MOH Medicines Formulary	<i>List the medicine(s) of the same/similar indication(s) or therapeutics class that are not listed in the MOHMF.</i>

3. SUPPORTING CLINICAL EVIDENCE (EFFICACY/ EFFECTIVENESS AND SAFETY)

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

- Submit studies most relevant to the indications and the population applied for. The most common sources of clinical evidence are:
 - Meta-analyses or systematic reviews of randomised controlled trials (RCTs).
 - RCTs of active-controlled trials (preferred).
 - 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
- 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).

- It is recommended that five (5) relevant studies (full text) to be submitted in both hardcopy and electronic form. These studies should address all aspects; clinical safety and efficacy/effectiveness of the medicine. These evidence should be summarised in an evidence table as shown in **Appendix 4**.
- 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 (if any) 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 5**.

4. SUPPORTING ECONOMIC EVIDENCE

4a) 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 (including pharmacoeconomic (PE) 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 6**.

The findings of economic evaluations conducted in other countries may not be directly applicable to the local setting due to major differences for example in 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 PE 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.

4b) 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 also 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 impact the trajectory of spending on that condition.

Some points to be considered when performing BIA:

- The information presented in BIA may assist the Pharmaceutical Services Division, Ministry of Health Malaysia 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).

**CHECKLIST OF INFORMATION INCLUDED IN DOSSIER FOR LISTING OF MEDICINE
INTO THE MOH MEDICINES FORMULARY**

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 (✓)	<i>Please provide reasons if the particulars are not submitted/ filled</i>
1.	Generic name of medicine (<i>including dosage form, strength, concentrations</i>)		
2.	Proprietary name		
3.	Registration holder		
4.	Manufacturer name and address		
5.	DCA registration number and date		
6(i)	DCA approved indication(s)		
6(ii)	Proposed indication (if different from DCA's)		
6(iii)	Restrictions of use		
6.	Declaration of products containing animal sources		
7.	DCA Approval Letter/ Certificate of renewal		
8.	DCA Approved product information leaflet		
9.	Information on formulary/ reimbursements in other countries with supporting documents		
10.	Dosing and administration (including subpopulation doses)		
11.	Proposed course of treatment (duration) and repeats if any		
12.	Name of principal pharmacological/ therapeutic class		
13.	Concomitant therapies		
14.	Co-administered therapies for side-effects		
15.	Contraindications		

NO	PARTICULARS	TICK (✓)	<i>Please provide reasons if the particulars are not submitted/ filled</i>
16.	Significant adverse effects		
17.	Warnings / Precautions		
18.	Interactions (Medicine/ Food/Disease)		
19.	Device requirement		
20.	Supply of device		
21.	Price per unit (SKU)		
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.	Price declaration form (Appendix 3)		
28.	Overview of disease		
29.	Rationale for listing application		
30.	Further elaboration on rationale for listing application		
31.	Existing medicines for same indication		
32.	Existing medicines in same therapeutic class		
33.	Non-pharmacological alternatives (is any)		
34.	Non-formulary comparators (if any)		
35.	Systematic search strategies for evidence		
36.	Supporting evidence for efficacy and safety: Recommended five (5) journals articles		
37.	Evidence tables for each research paper		
38.	Clinical trial/ study reports conducted in Malaysia (if any)		
39.	Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)		
40.	Economic evaluations/ reports		
41.	Evidence tables of PE studies		
42.	Budget impact analysis		
43.	Financial implication of proposed drug vs. comparator/ current management		

NO	PARTICULARS	TICK (✓)	<i>Please provide reasons if the particulars are not submitted/ filled</i>
44.	(Applicant Statement of Declaration) Signature, stamp and contact details of the proposer		
45.	Post Marketing Safety Reports		
46.	CD/Softcopy of dossier (including research papers and economic models if any)		
47.	Sample of drug (one unit only with packaging/ box) if requested		
48.	List of references in Vancouver style		
49.	Relevant treatment guidelines if available		
50.	<p>Payment Information:</p> <p>Bank draft/ money order/postal order made payable to 'KETUA SETIAUSAHA, KEMENTERIAN KESIHATAN MALAYSIA'.</p> <p>() 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]</p> <p>Bank draft no./money order no./postal order no.: _____</p> <p><i>Please refer to the guideline for details of the fee.</i></p>		
Filled in by / Date :			

NOTE: Incomplete applications will not be processed.

FOR OFFICE USE ONLY (SECRETARIAT)	
Date received :	Comment :
Registration number :	
Checked by :	

PART B (D2): GUIDELINES FOR PREPARING DOSSIER D2

To Add or Amend Formulation/Dosage Form/Strength of Medicines Listed in the MOH Medicines Formulary

1. MEDICINE INFORMATION

Instructions

- Applicant should provide detailed information about the medicine as required in the form below.
- 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: <i>Provide full generic name of the medicine. List each formulation/dosage form /strength applied for on separate rows.</i>
		Existing medicine in MOHMF: <i>State all the formulation / dosage form / strength currently available in MOHMF.</i>
2	Proprietary Name	<i>State the trade name of the medicine registered in Malaysia.</i>
3	Registration Holder	<i>State the company name and address.</i>
4	Manufacturer	<i>State the company name and address.</i>
5	DCA Registration No.	<i>State the DCA Registration number and registration date. (Attach the DCA Approval Letter/ Latest certificate of renewal with full indication). *DCA: Drug Control Authority.</i>
6	i) Approved Indication(S)	<i>DCA Approved Indication(s): List all the DCA approved indication(s) of the medicines. To obtain certified document from the DCA.</i>
		<i>Indication(s) in MOHMF: State current indication(s) listed in MOHMF.</i>
	ii) Restrictions of Use (if any)	<i>State any 'restrictions of use' that are considered in prescribing this medicine for example for group of patients (age, sex, conditions etc), severity of disease, stages of treatment etc.</i>

7	Declaration of Products Containing Animal Sources	<i>State the origins of the ingredients used in preparing the medicines.</i>
---	---	--

B. CLINICAL AND PHARMACOLOGICAL INFORMATION

1	Dosing and Administration (dose, frequency, route of administration)	<i>State the dose frequency and route of administration for the medicine in all population groups for each indication.</i>
	1a. Adult Dose	
	1b. Paediatric Dose (if applicable)	
	1c. Dose in Renal Impairment	
	1d. Dose in Liver Failure	
	1e. Others (if any)	
2	Proposed Course of Treatment (duration) and Repeats if any	<i>State the recommended duration of treatment and treatment cycle (if any). State 'life-long' if the medicine will be used continuously by patient.</i>
3	Other Relevant Information (if any)	

C. SPECIAL DEVICE (if any)

1	Device Requirement	<i>State if the medicine needs special device. If yes, please provide detail information.</i>
2	Supply of Device	<i>State the supply mechanism of the above said device (e.g.: Free of charge, to be purchased separately).</i>

2. RATIONALE FOR APPLICATION AND COMPARATORS

2a. OVERVIEW OF THE DISEASE AND CURRENT MANAGEMENT

- Provide an overview of the disease and the patient population that the product is targeted for treatment.
- Provide data on disease prevalence and epidemiology in Malaysia.
- Provide brief overview on the current disease management.
- Other relevant information

2b. RATIONALE FOR LISTING APPLICATION

Tick (√) the main reason(s) to list the product:	
<input type="checkbox"/>	Has therapeutic advantage over an existing medicine(s).
<input type="checkbox"/>	A cheaper alternative to an existing medicine(s).
<input type="checkbox"/>	Insufficiently treated condition.
<input type="checkbox"/>	Improve compliance.
<input type="checkbox"/>	New innovation medicine.
<input type="checkbox"/>	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).

3. SUPPORTING CLINICAL EVIDENCE (EFFICACY/ EFFECTIVENESS AND SAFETY)

(It is recommended that three (3) relevant studies that provide evidence on the advantages of proposed formulation/strength/dosage form to be submitted)

- 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).
- Information from all relevant studies should be summarised in evidence tables. Use one table for each study. A standard evidence table format can be found in **Appendix 4**. Include both efficacy/ effectiveness and safety outcome measures.
- Level of evidence for all studies and reviews should be classified based on categories as 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.

4. SUPPORTING ECONOMIC EVIDENCE

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.

4a. MEDICINE AND TREATMENT RELATED COSTS		
1	Price Per Unit (RM): (a)	<i>State the nett price to MOH institutions, inclusive of all fees. Submit details as required in Medicine Price Declaration Form (Appendix 3). Use separate form for each item (dosage form/ strength).</i>
2	Number of Dosage Units Administered Per Day or Per Cycle (b)	<i>State the number (or average number) of dosage units administered per day or per cycle.</i>
3	Average Duration of Treatment in Days or Cycles Per Year (c)	<i>State the average duration of treatment in days or no of cycles per year. If the treatment is continuous for 1 year, use 365 days. If the product is an antibiotic, state number of days per treatment.</i>

4	Total Medicine Cost Per Patient Per Year (d) d = a x b x c	<i>This can be calculated by multiplying a, b and c</i>
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.	<i>List all the potential additional costs. Calculate the potential additional costs per patient per year. This may include cost of monitoring, drug administration cost, cost of additional equipment required, costs to control adverse effects etc.</i> <i>If no published data is available, estimates can be used. However, estimates need to be justified.</i>
6	Total Annual Cost Per Patient (f)	f = (d + e)

4b. 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 6** for the format to report economic evaluations. Full text of these documents (if any) can be included in the electronic copy of the dossier.

5. APPLICANT'S STATEMENT OF DECLARATION

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

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:

Company's Stamp:

Company Address:

**CHECKLIST OF INFORMATION INCLUDED IN DOSSIER FOR LISTING OF MEDICINE INTO
THE MINISTRY OF HEALTH MEDICINES FORMULARY**

**DOSSIER 2 (D2): PROPOSAL TO ADD OR AMEND FORMULATION / DOSAGE FORM /
STRENGTH OF MEDICINES ALREADY LISTED IN THE MINISTRY OF
HEALTH MEDICINES FORMULARY**

MEDICINE NAME:	
COMPANY NAME:	

NO	PARTICULARS	TICK (✓)	<i>Please provide reasons if the particulars are not submitted/ filled</i>
1.	Generic name: Proposed dosage form(s) & strength(s)/ concentration(s)		
2.	Currently available dosage form(s) & strength(s)/ concentration(s) in MOHMF		
3.	Proprietary name		
4.	Registration holder		
5.	Manufacturer		
6.	DCA Registration No.		
7.	i) Approved indication(s) ii) Restrictions of use (if any)		
8.	DCA approval letter/ Certificate of renewal		
9.	DCA approved product information leaflet		
10.	Restrictions of use		
11.	Formulary/ Reimbursements in other countries with supporting documents		
12.	Dosing and administration (including subpopulation doses)		
13.	Proposed course of treatment (duration) and repeats if any		
14.	Device requirement		
15.	Supply of device		
16.	Overview of disease		

NO	PARTICULARS	TICK (✓)	<i>Please provide reasons if the particulars are not submitted/ filled</i>
17.	Rationale for listing application		
18.	Further elaboration on rationale for listing application		
19.	Information on systematic search strategies for evidence conducted		
20.	Supporting evidence for efficacy and safety: Recommended three (3) journals articles		
21.	Evidence tables for the above for each research paper		
22.	Clinical trial/ study reports conducted in Malaysia		
23.	Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)		
24.	Price Per Unit (SKU)		
25.	Number dosage units per day or per cycle		
26.	Average duration of treatment in days or cycles per year		
27.	Total cost per patient per year		
28.	Additional cost per patient per year		
29.	Total annual cost per patient		
30.	Price Declaration Form (Appendix 3)		
31.	Economic evaluations/ reports (if any)		
32.	Evidence tables of PE studies /format in reporting economic evaluations (if any)		
33.	Budget implications		
34.	Financial implication of proposed drug vs. comparator/ current management		
35.	Signature, stamp and contact details of the proposer		
36.	Post Marketing Safety Reports		
37.	CD/Softcopy of dossier (including research papers and economic models if any)		
38.	Sample of drug (one unit only with packaging/ box)		
39.	List of references in Vancouver style		
40.	Relevant treatment guidelines (if available)		

NO	PARTICULARS	TICK (✓)	<i>Please provide reasons if the particulars are not submitted/ filled</i>
41.	<p>Payment Information:</p> <p>Bank draft/ money order/postal order made payable to 'KETUA SETIAUSAHA, KEMENTERIAN KESIHATAN MALAYSIA'.</p> <p>() RM 2,000.00 [Proposal to add or amend formulation/dosage form/strength of medicines listed in the MOH Medicines Formulary]</p> <p>Bank draft no./money order no./postal order no.: _____</p> <p><i>Please refer to the guideline for details of the fee.</i></p>		
<p>Filled in by :</p> <p>Date :</p>			

NOTE: Incomplete applications will not be processed.

FOR OFFICE USE ONLY (SECRETARIAT)	
Date received :	Comment :
Registration number :	
Checked by :	

PART B (D3): GUIDELINES FOR PREPARING 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	<i>Provide full generic name as available in MOHMF. Provide MDC code for easy identification of the medicine.</i>	
2	Indication(s) as in MOH Medicines Formulary	<i>State the corresponding indication(s) of the medicine proposed to be changed category of prescriber in MOHMF.</i>	
3	Currently Available Brands and Manufacturer	<i>State the brand name of the medicine and the manufacturer. For non-patented medicine state the generics that are available.</i>	
4	Restrictions of Use (if any)	<i>State any 'restrictions of use' that are going to be imposed in prescribing this medicine for example for group of patients (age, sex, conditions etc.), severity of disease, stages of treatment etc.</i>	
5	Category of Prescriber	Existing category of prescriber in MOHMF:	
		Proposed category of prescriber:	
6	Existing Medicines in the Proposed Category of Prescriber	<i>State the alternatives in the MOHMF with the same indication and proposed category of prescriber.</i>	
7	Is the Medicine a Replacement for Existing Alternative in MOHMF?	No	Yes:
			<i>(Suggest medicine(s) that can be replaced, fill in Form D5)</i>

8	The Main Reason(s) for this Proposal <i>Select the main reason(s) of the proposal.</i>		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).

B. CLINICAL AND PHARMACOLOGICAL INFORMATION

1	Dosing and Administration (Dose, Frequency)	<i>State the dose and frequency for the medicine in all population groups for each indication.</i>
1a	Adult Dose	
1b	Paediatric Dose (if applicable)	
2	Course of Treatment (Duration) and Repeats if any	<i>State the recommended duration of treatment when using the medicine and potential or recommended treatment cycle (if any). State life-long if the medicine will be used continuously by patient.</i>
3	Concomitant Therapies (If any)	<i>If the medicine is to be used in combination with other therapies, state (if any) the concomitant therapies with the dosage, frequency and duration.</i> <i>If the medicine is used for more than one proposed indication, state the concomitant therapies by indications.</i>
4	Co-administered Therapies to Manage Side-Effects	<i>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)</i>

5	Contraindications	<i>State all contraindications when taking this medicine as approved by DCA. Provide references.</i>
6	Significant Adverse Effects	<i>State the significant adverse reactions, references as approved by DCA and Post Marketing Surveillance reports available.</i>
7	Warnings / Precautions	<i>State all warnings and precautions associated with the medicine as approved by DCA and references.</i> <i>State any changes have been made since marketing authorization received from DCA.</i>
8	Interactions (Medicine/ Food/Disease)	<i>State the significant interaction(s) between medicine/ food/ disease with complete reference details.</i>
C. SPECIAL DEVICE (if any)		
1	Device Requirement	<i>State if the medicine need special device. If it is, please provide detailed information.</i>

2. SUPPORTING CLINICAL EVIDENCE (EFFICACY/ 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, besides the effectiveness, safety issues would be the main concern.

The most relevant, clear, latest and unbiased evidence should be submitted to support the application. Relevant documents regarding efficacy/ effectiveness and safety should be submitted in both hard copy and electronic form.

- 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 (eg. language, year).
- It is recommended that one (1) relevant study (full text) to be submitted in both hard copy and electronic form. These studies should address aspects relevant to the application submitted on clinical safety, efficacy/effecutiveness and/ or applicability of medicine. These evidence should be summarised in evidence tables as in **Appendix 4**.
- Level of evidence for all studies and reviews should be classified based on categories as 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.
- 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.

3. SUPPORTING ECONOMIC EVIDENCE

Details on costs of medicines and any other costs related to the treatment should be stated using the format in the table below.

The main concern to MOH when changing prescriber category of medicines would be the impact of the change to the overall medicine expenditure. Thus, budget implications due to the change in prescriber category of the medicines should also be projected.

3a. MEDICINE, RELATED TREATMENT COSTS AND BUDGET IMPLICATIONS		
1	Price Per Unit (RM): (a)	<i>State the nett price to MOH institutions, inclusive of all fees. Submit details as required in Medicine Price Declaration Form (Appendix 3). Use separate form for each item (dosage form/ strength).</i>
2	Number of Dosage Units Administered Per Day or Per Cycle (b)	<i>State the number (or average number) of dosage units administered per day or per cycle.</i>
3	Average Duration of Treatment in Days or Cycles Per Year (c)	<i>State the average duration of treatment in days or no of cycles per year. If the treatment is continuous for 1 year, use 365 days. If the product is an antibiotic, state number of days per treatment.</i>
4	Total Medicine Cost Per Patient Per Year (d) $d = a \times b \times c$	<i>This can be calculated by multiplying a, b and c</i>
5	Additional Cost Per Patient Per Year (e) Data sources not limited to the MOH facilities (eg MOHE, MOD or private setting). Data sources must be reported.	<i>List all the potential additional costs. Calculate potential additional costs per patient per year. This may include cost of monitoring, drug administration cost, cost of additional equipment required, costs to control adverse effects etc.</i> <i>If no published data is available, estimates can be used. However, estimates need to be justified.</i>
6	Total Annual Cost Per Patient (f)	$f = (d + e)$

7	Total Procurement Last Year (institution) if any	Year: RM
8	Expected Number of Patients Per Year (institution)	<i>State the expected number of patients (in your institution) to be on the medicine when prescriber category is changed.</i>
9	Expected New Expenditure that will be Incurred for the Applied Medicine Per Year (institution)	<i>State the expected expenditure (in your institution) that will be incurred (on the medicine) when prescriber category is changed.</i>

3b. 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 6** for the format to report economic evaluations. Full text of these documents (if any) can be included in the electronic copy of the dossier.

4. 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:	

Medicine name:

5. HEAD OF DEPARTMENT

SUPPORT

NOT SUPPORT

Comment:
.....

Signature:

Date:

Name & Stamp:

6. HEAD OF PHARMACY DEPARTMENT

SUPPORT

NOT SUPPORT

Comment:
.....

Signature:

Date:

Name & Stamp:

7. HEAD OF INSTITUTION

SUPPORT

NOT SUPPORT

Comment:
.....

Signature:

Date:

Name & Stamp:

8. CHAIRMAN OF STATE DRUGS & THERAPEUTIC COMMITTEE

[where applicable]

SUPPORT

NOT SUPPORT

Comment:

.....

Signature:

Date:

Name & Stamp:

**CHECKLIST OF INFORMATION INCLUDED IN DOSSIER FOR LISTING OF MEDICINE INTO
THE MINISTRY OF HEALTH MEDICINES FORMULARY**

**DOSSIER 3 (D3): TO CHANGE CATEGORY OF PRESCRIBER OF MEDICINES IN THE
MINISTRY OF HEALTH MEDICINES FORMULARY**

MEDICINE NAME:	
INSTITUTION:	

NO	PARTICULARS	TICK (✓)	<i>Please provide reasons if the particulars are not submitted/ filled</i>
1.	Generic name and MDC code		
2.	Indication(s) as in MOH Medicines Formulary		
3.	Restrictions of use (if any)		
4.	Proprietary name and manufacturer		
5.	Existing medicines (same indication) in same proposed category		
6.	Alternative to replace (if any)		
7.	The main reason(s) to change prescriber category		
8.	Other justifications of the proposal		
9.	DCA approved product information leaflet		
11.	Dosing and administration (including subpopulation doses)		
12.	Proposed course of treatment (duration) and repeats if any		
13.	Device requirement		
14.	Information on systematic search strategies for evidence conducted		
15.	Supporting evidence for efficacy and safety: Recommended one (1) journal article		
16.	Evidence tables for each research paper		
17.	Clinical trial/ study reports conducted in Malaysia (if any)		
18.	Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)		
19.	Price per unit (SKU)		
20.	Number dosage units per day or per cycle		
21.	Average duration of treatment in days or cycles per year		
22.	Total cost per patient per year		

NO	PARTICULARS	TICK (✓)	<i>Please provide reasons if the particulars are not submitted/ filled</i>
23.	Additional cost per patient per year		
24.	Total annual cost per patient		
25.	Total procurement last year (institution) if any		
26.	Expected number of patients per year (institution)		
27.	Expected new expenditure that will be incurred for the applied medicine per year (institution)		
28.	Price Declaration Form (Appendix 3)		
29.	Economic evaluations/ reports (if any)		
30.	Evidence Tables of PE studies /format in reporting economic evaluations (if any)		
31.	Statement of Declaration		
32.	Signature, stamp and contact details of the proposer		
33.	CD/Softcopy of dossier (including research papers and economic models if any)		
34.	List of references in Vancouver style		
35.	Relevant treatment guidelines (if any)		
Filled in by / Date :			

NOTE: Incomplete applications will not be processed.

FOR OFFICE USE ONLY (SECRETARIAT)	
Date received :	Comment :
Registration number :	
Checked by :	

PART B (D4): GUIDELINES FOR PREPARING DOSSIER D4

To Add Approved Medicines in the MOH Medicines Formulary into Institution's Medicines Formulary

Background

A medicine is eligible for consideration to be added into institution's⁶ Medicines Formulary only when it is listed in the MOHMF.

The form below is to be used by the applicants (consultants/ specialists/ medical officers/ pharmacists) for the purpose of listing into institution's Medicines Formulary. The form should be submitted to The Secretariat of the institution's Medicines and Therapeutics Drug Committee (DTC). The Secretariat will present a brief review of the application in the DTC meeting for listing 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.

⁶ Include hospitals, health clinics and special medical institution (for example National Cancer Institute, Institute of Respiratory Medicines).

A. MEDICINE PARTICULARS (to be filled by applicant)				
1	Generic name [specify dosage form(s) & strength(s)/ concentration(s)]	<i>Provide full generic name as available in MOHMF with the dosage form(s), strength(s) and concentration(s).</i>		
2	Indication(s) approved for MOH Medicines Formulary	<i>State all indication(s) to be proposed for listing in the institution's Medicines Formulary. The indications should be the indications approved.</i>		
3	Approved category of prescriber	<i>State the approved prescriber category as in the MOHMF.</i>		
4	Brand name	<i>State the medicine brand name as marketed in Malaysia.</i>		
5	Dosing, frequency and duration of treatment			
6	Existing medicine(s) with the same/ similar indication & annual procurement <i>Add more lines if there are more than 3 alternatives currently available in the institution's Medicines Formulary</i>	Generic name 1:		
		Year: RM		
7	The main reason(s) to list the product: <i>Please tick the main reason of the proposal.</i>	Has therapeutic advantage over an existing drug		
		A cheaper alternative to an existing drug		
8	Is this a replacement for existing medication?	Improve compliance		
		Others (please specify below):		
9	Other details on rationale of application:	<table border="1"> <tr> <td>No</td> <td>Yes: <i>(medicines that can be deleted)</i></td> </tr> </table>	No	Yes: <i>(medicines that can be deleted)</i>
No	Yes: <i>(medicines that can be deleted)</i>			
9	Other details on rationale of application:			

B. COSTS AND BUDGET IMPLICATION TO THE INSTITUTION		
1	Estimated number of patients per year (a)	1. <i>(for therapeutic discipline 1)</i> 2. <i>(for therapeutic discipline 2)</i>
2	Price per pack size (RM)	<i>State the SKU and the medicine costs per SKU unit agreed for MOHMF.</i>
3	Dosing, frequency and duration of treatment	<i>Refer to sec. A</i>
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	<i>The budget available for disciplines that are going to use the medicines should be stated</i> 1. 2.

C. APPLICANT'S STATEMENT OF DECLARATION

STATEMENT OF DECLARATION	
<p>I, the undersigned, declare herewith that to my best knowledge and professional responsibility all information submitted within this dossier is complete and correct.</p>	
Signature:	Date:
Name of Officer:	Contact Number:
Designation:	Email Address:
Official Stamp:	

Medicine Name:

D. HEAD OF DEPARTMENT

SUPPORT

NOT SUPPORT

Comment:
.....

Signature:

Date:

Name & Stamp:

E. HEAD OF PHARMACY DEPARTMENT

SUPPORT

NOT SUPPORT

Comment:
.....

Signature:

Date:

Name & Stamp:

F. APPROVAL BY THERAPEUTIC & DRUGS COMMITTEE

APPROVE

NOT APPROVE

Comments:
.....
.....

Signature (Chairperson):

Meeting Date:

Name & Stamp:

PART B (D5): GUIDELINES FOR PREPARING DOSSIER D5

To Delist Approved Medicine(s)/ Indication(s) From the MOH Medicines Formulary

When submitting a proposal to delist any medicine from the MOHMF, the form Dossier D5 below should be used. Any relevant supporting documents should be submitted with the dossier.

Instructions

- 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)]	<i>Provide full generic name as available in MOHMF.</i>	
2	Malaysian Drug Code	<i>Provide the MDC of the medicine as in the MOHMF.</i>	
3	Indication(s) to be Deleted	<i>Specify the indication in MOHMF to be deleted or state all the indications if the medicine is to be deleted</i>	
4	Category of Prescriber		
5	Is this Medicine or Indication used by other Discipline?	NO:	YES: <i>State the discipline</i>
6	Other Relevant Information (if any)		

B. RATIONALE FOR DELETION	
<i>Include any supporting documents (if any)</i>	

C. 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:

D. OTHER REMARKS (IF ANY)	

E. APPLICANT'S STATEMENT OF DECLARATION

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

STATEMENT OF DECLARATION	
<p>I, the undersigned, declare herewith that to my best knowledge and professional responsibility all information submitted within this dossier is complete and correct.</p>	
<p>Medicine Name:</p>	
Signature:	Date:
Name of Officer:	Contact Number:
Designation:	Email Address:
Official Stamp:	Address:

Medicine Name:

F. HEAD OF DEPARTMENT

SUPPORT

NOT SUPPORT

Comment:
.....

Signature:

Date:

Name & Stamp:

G. HEAD OF PHARMACY DEPARTMENT

[for application from MOH Institution]

SUPPORT

NOT SUPPORT

Comment:
.....

Signature:

Date:

Name & Stamp:

Medicine Name:

H. HEAD OF INSTITUTION

[for application from MOH Institution]

SUPPORT

NOT SUPPORT

Comment:

.....

Signature:

Date:

Name & Stamp:

I. CHAIRMAN OF STATE DRUGS & THERAPEUTIC COMMITTEE

[where applicable]

SUPPORT

NOT SUPPORT

Comment:

.....

Signature:

Date:

Name & Stamp:

NOTE: Incomplete application will not be processed.

FOR OFFICE USE ONLY (SECRETARIAT)

Date received :

Comment :

Registration number :

Checked by :

APPENDICES

APPENDIX 1: LETTER OF INTENT FORMAT

Date:

Company/ Institution letter head

Secretariat
MOH Medicines Formulary Review Panel
Pharmaceutical Services Division
Ministry of Health Malaysia
Lot 36 Jalan Universiti
46350 Petaling Jaya.

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 the purpose of 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:

Name & Address of Manufacturer:

Name & Address of Registration Holder:

DCA Registration Number: MAL.....

DCA Approved Indication(s):

***Type of Dossier to be submitted: D1 (to list new medicine/ to add indication(s))/D2/D3**

***Resubmission: YES/NO (If yes, date of previous submission _____)**

2. I declare that the medicine has fulfilled all seven (7) eligibility criteria listed in the Submission Guideline (as per Appendix 1a).

3. As required, a completed specialist/ consultant support form is attached (as per Appendix 2).

Thank you.

Sincerely,

.....

Name:

Designation:

Telephone No.:

Email Address:

*Please select one

Appendix 1(a): Seven (7) Eligibility Criteria for Medicines Intended to be Applied for Listing into the MOH Medicines Formulary

NO.	CRITERIA	YES/NO	COMMENT
1	Medicines Must be Registered With The Drug Control Authority (DCA) In Malaysia For at Least 12 Months.		
2	Indications 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 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.		
5	Medicines Must Have been Used for at Least 12 Months in Malaysia Post DCA Registration. An Updated Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER) Must be Made Available.		
6	Medicines Must Have Therapeutic Advantage Supported by Scientific Evidences.		
7	Each Application Must be Supported by at Least 2 Clinical Consultants/ Specialists of The Respective Field Working in 2 Different Ministry of Health Malaysia Institutions.		

*Any countries. State the country referenced and provide supporting evidence.

APPENDIX 2: SUPPORTING DOCUMENT FROM SPECIALIST/ CONSULTANT

EXPERT OPINION PROPOSAL TO INTRODUCE A NEW MEDICINE INTO MINISTRY OF HEALTH MEDICINES FORMULARY

A. MEDICINE PARTICULARS		
1	Medicine Name & Strength Proprietary Name	
2	Registration holder & Manufacturer	
3	i) DCA Approved Indication(s)	
	ii) Proposed Indication(s) for the MOH Medicines Formulary	
4	iii) Restrictions of Use (if any)	

B. EXPERT OPINION		
1	Experience of using this medicine :	() Yes () No Hospital/Institution : Duration of use : Comment:
2	Efficacy in comparison with standard medicine treatment and/or current available medicine(s) Name the current standard treatment:	() More effective () Effective () Less effective () Limited efficacy () Similar efficacy Comment:
3	Base on your experience/opinion, do you think this medicine should be listed in MOH Medicines Formulary?	() Yes () No Reasons:
4	What is the percentage of your patient suitable for the medicine?	

5	Are there any new alternatives available for same/ similar indication?	
6	Current and Potential Off-label Use and potential abuse (if available)	
7	Is there any existing medicine that is recommended to be deleted from MOH Medicines Formulary	

C. DECLARATION OF POTENTIAL CONFLICT OF INTEREST

I declare a potential conflict of interest : NO

YES, please provide details below:

Financial or other interest from contact with pharmaceutical companies, which may have bearing on this submission:

Research support

Current financial interest eg shares or bonds in commercial entity with interest in subject matter

Employment, consultancy, directorship, or other position during the past 4 years, whether or not paid

Close family member employed in the related company as senior manager /board of directors

Others, please specify:

Declared by:

Signature :

Date:

Name & official stamp :

APPENDIX 3: MEDICINE 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 0.4% e-Perolehan Fee)		
8	Price Per Unit (RM) (Inclusive of 0.4% e-Perolehan Fee)		
9	Public Wholesale Price per unit (RM) in TWO in ASEAN countries	1. 2.	
10	Public Wholesale Price per unit (RM) in TWO <i>*peer / * similar economic status</i> Countries from Other Region	1. 2.	
11	Public Wholesale Price per unit (RM) in Country of Origin		
12	Patent validity date		

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

NOTE:

- 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) year from the date of the circular on the listing of medicine(s) in the MOH Medicines Formulary.
- Notification on the medicine price listed in MOH Medicines Formulary will be issued by Medicine Price Branch, Pharmaceutical Service Division.
- Any offers for patient assisted programme should be explicitly declared and detailed.

APPENDIX 4: EVIDENCE TABLE (EFFICACY/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 5: 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 6: 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 7: WORKFLOW OF APPLICATION OF DOSSIER D3 & D5 BY MOH INSTITUTIONS

