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

Pharmaceutical Services Division
Ministry of Health Malaysia
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.

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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’s\(^1\) 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:

<table>
<thead>
<tr>
<th>Type of dossier</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>Pharmaceutical industries</td>
</tr>
<tr>
<td>D2</td>
<td>Pharmaceutical industries</td>
</tr>
<tr>
<td>D3</td>
<td>MOH(^2) only</td>
</tr>
<tr>
<td>D4</td>
<td>MOH(^2) only</td>
</tr>
<tr>
<td>D5</td>
<td>Pharmaceutical industries or MOH(^2)</td>
</tr>
</tbody>
</table>

---

\(^1\) 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

Start

Receive LOI from Applicant

Screen LOI

NO

LOR

Not eligible to submit

Evaluate Dossier

Feedback: Relevant Units

Compile Information

Yes

Complete

Return To Applicant

Eligible to submit

Receive Full Dossier from Applicant

NO

LOA

MOH Formulary Secretariat

MOH Formulary Secretariat

MOH Formulary Secretariat

MOH Formulary Secretariat

MOH Formulary Secretariat/Pharmacoeconomics Unit

MOH Formulary Secretariat

1. TDW Committee
2. DE Committee

MOH Formulary Secretariat

MOH Formulary Secretariat

MOH Formulary Secretariat

MOH Formulary Secretariat

MOH Formulary Secretariat

MOH Formulary Secretariat

MOH Formulary Secretariat

MOH Formulary Secretariat

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

Guidelines for Submission of Dossier for Listing into the 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 institutions\(^3\) 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.

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\(^3\) 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>
<thead>
<tr>
<th>Meeting No</th>
<th>Planned Panel Meeting Date</th>
<th>Submission Cut-off Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>March</td>
<td>1st December</td>
</tr>
<tr>
<td>2</td>
<td>July</td>
<td>1st April</td>
</tr>
<tr>
<td>3</td>
<td>November</td>
<td>1st August</td>
</tr>
</tbody>
</table>

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.

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

*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
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**

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

*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 DCA\(^5\) approved package insert must be attached.
- Sample of medicine should be provided upon request by The Secretariat.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. MEDICINE PARTICULARS</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td><strong>Generic Name</strong> [specify dosage form(s) &amp; strength(s)/ concentration(s)]</td>
</tr>
<tr>
<td>2</td>
<td><strong>Proprietary Name</strong></td>
</tr>
<tr>
<td>3</td>
<td><strong>Registration Holder</strong></td>
</tr>
<tr>
<td>4</td>
<td><strong>Manufacturer</strong></td>
</tr>
<tr>
<td>5</td>
<td><strong>DCA Registration No.</strong></td>
</tr>
<tr>
<td>6</td>
<td>i) <strong>DCA Approved Indication(s)</strong></td>
</tr>
<tr>
<td></td>
<td>ii) <strong>Proposed Indication(s) for the MOH Medicines Formulary (MOHMF)</strong></td>
</tr>
<tr>
<td></td>
<td>iii) <strong>Restrictions of Use (if any)</strong></td>
</tr>
</tbody>
</table>

---

\(^5\) DCA: Drug Control Authority of Malaysia
7. Declaration of products containing animal sources

State the origins of the ingredients used in preparing the medicine.

8. Formulary/Reimbursement in other countries

<table>
<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>
</tbody>
</table>

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.

Attach supporting evidence.

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.

1a. Adult Dose

1b. Paediatric Dose (if applicable)

1c. Dose in Renal Impairment

1d. Dose in Liver Failure

1e. Others (if any)
<table>
<thead>
<tr>
<th></th>
<th>Provisions</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Proposed course of treatment (Duration) and repeats if any</td>
<td>State the recommended duration of treatment and treatment cycle (if any). 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</td>
<td>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).</td>
</tr>
<tr>
<td>5</td>
<td>Co-administered Therapies to manage side-effects</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>
<tr>
<td>7</td>
<td>Adverse Reactions</td>
<td>State all adverse reactions. Provide Periodic Safety Update Report (PSUR) or Periodic Benefit-Risk Evaluation Report (PBRER).</td>
</tr>
<tr>
<td>8</td>
<td>Warnings / Precautions</td>
<td>State all warnings and precautions. Provide references. State any changes have been made since marketing authorization received from DCA.</td>
</tr>
<tr>
<td>9</td>
<td>Interactions (Medicine/ Food/Disease)</td>
<td>State the significant interaction(s) between medicine/ food/ disease. Provide references.</td>
</tr>
</tbody>
</table>

C. SPECIAL DEVICE (if any)

<p>|   | Device Requirement                                                      | State if the medicine needs special device. If yes, please provide detailed information.                                                                                                               |</p>
<table>
<thead>
<tr>
<th></th>
<th>Supply of Device</th>
<th>State the supply mechanism of the above said device (e.g.: Free of charge, to be purchased separately)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.</td>
<td>MEDICINE AND RELATED TREATMENT COSTS</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Price Per Unit (RM): $(a)$</td>
<td>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).</td>
</tr>
<tr>
<td>2</td>
<td>Number of dosage units administered per day or per cycle $(b)$</td>
<td>State the number (or average number) of dosage units administered per day or per cycle.</td>
</tr>
<tr>
<td>3</td>
<td>Average duration of treatment in days or cycles per year $(c)$</td>
<td>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.</td>
</tr>
<tr>
<td>4</td>
<td>Total medicine cost per patient per year $(d)$</td>
<td>This can be calculated by multiplying $a$, $b$ and $c$</td>
</tr>
<tr>
<td>$d = a \times b \times c$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Additional cost per patient per year $(e)$</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Data sources not limited to the MOH facilities (e.g. MOHE, MOD or private setting). Data sources must be reported.</td>
<td>If no published data is available, estimates can be used. However, estimates need to be justified.</td>
</tr>
<tr>
<td>6</td>
<td>Total annual cost per patient $(f)$</td>
<td>$f = (d + e)$</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Tick(✓) the main reason(s) to list the product:</th>
</tr>
</thead>
<tbody>
<tr>
<td>New innovator medicine.</td>
</tr>
<tr>
<td>Has therapeutic advantage over an existing medicine(s).</td>
</tr>
<tr>
<td>A cheaper alternative to an existing medicine(s).</td>
</tr>
<tr>
<td>Insufficiently treated condition.</td>
</tr>
<tr>
<td>Improve compliance.</td>
</tr>
<tr>
<td>Others (specify below):</td>
</tr>
</tbody>
</table>

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).*
2c. EXISTING TREATMENT/ MEDICINE(S)

<table>
<thead>
<tr>
<th>Existing Treatment/ Medicine(s) for the same/similar indication(s) in MOH MEDICINES FORMULARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>[specify strength &amp; dosage form]</td>
</tr>
<tr>
<td>Existing medicine(s)/ comparator(s) for the same/similar indication(s)</td>
</tr>
<tr>
<td>• List all the existing medicine(s) in MOHMF with the same/similar indication(s). Provide medicine names, strengths and dosage forms.</td>
</tr>
<tr>
<td>• If there are more than one proposed indication, state the comparators by each indication in separate tables.</td>
</tr>
<tr>
<td>Other alternatives (non-pharmacological)</td>
</tr>
<tr>
<td>List all non-pharmacological therapies which can be used for the same indication (if any).</td>
</tr>
<tr>
<td>Other medicine(s) with the same/similar indication not listed in the MOH Medicines Formulary</td>
</tr>
<tr>
<td>List the medicine(s) of the same/similar indication(s) or therapeutics class that are not listed in the MOHMF.</td>
</tr>
</tbody>
</table>

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).
• Full disclosure of methodology including calculation and uncertainty should be provided in an 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.

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.
v) Estimating changes in disease related costs.

For more information on principles of conducting a BIA, refer to:

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

<table>
<thead>
<tr>
<th>STATEMENT OF DECLARATION</th>
</tr>
</thead>
</table>

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: ……………………………
Position: …………………………… Email Address: ……………………………
Company’s Stamp: …………………………… Company Address: ……………………………
# 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**

<table>
<thead>
<tr>
<th>NO</th>
<th>PARTICULARS</th>
<th>TICK (✓)</th>
<th>Please provide reasons if the particulars are not submitted/ filled</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Generic name of medicine (<em>including dosage form, strength, concentrations</em>)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Proprietary name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Registration holder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Manufacturer name and address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>DCA registration number and date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6(i)</td>
<td>DCA approved indication(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6(ii)</td>
<td>Proposed indication (if different from DCA’s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6(iii)</td>
<td>Restrictions of use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Declaration of products containing animal sources</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>DCA Approval Letter/ Certificate of renewal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>DCA Approved product information leaflet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Information on formulary/ reimbursements in other countries with supporting documents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Dosing and administration (including subpopulation doses)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Proposed course of treatment (duration) and repeats if any</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Name of principal pharmacological/ therapeutic class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Concomitant therapies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Co-administered therapies for side-effects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Contraindications</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Medicine Name:**

**Company Name:**
<table>
<thead>
<tr>
<th>NO</th>
<th>PARTICULARS</th>
<th>TICK (√)</th>
<th>Please provide reasons if the particulars are not submitted/ filled</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Significant adverse effects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Warnings / Precautions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Interactions (Medicine/ Food/Disease)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Device requirement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Supply of device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Price per unit (SKU)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Number of dosage units per day or per cycle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Average duration of treatment in days or cycles per year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Total cost of medicine per patient per year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Additional cost per patient per year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>Total annual cost per patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>Price declaration form (Appendix 3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>Overview of disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>Rationale for listing application</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>Further elaboration on rationale for listing application</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>Existing medicines for same indication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>Existing medicines in same therapeutic class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>Non-pharmacological alternatives (is any)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>Non-formulary comparators (if any)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>Systematic search strategies for evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>Supporting evidence for efficacy and safety: Recommended five (5) journals articles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>Evidence tables for each research paper</td>
<td></td>
<td></td>
</tr>
<tr>
<td>38</td>
<td>Clinical trial/ study reports conducted in Malaysia (if any)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>Periodic Safety Update Reports (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>Economic evaluations/ reports</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>Evidence tables of PE studies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>42</td>
<td>Budget impact analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>43</td>
<td>Financial implication of proposed drug vs. comparator/ current management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td>PARTICULARS</td>
<td>TICK (✓)</td>
<td>Please provide reasons if the particulars are not submitted/ filled</td>
</tr>
<tr>
<td>----</td>
<td>---------------------------------------------------------------------------</td>
<td>----------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>44</td>
<td>(Applicant Statement of Declaration) Signature, stamp and contact details of the proposer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>45</td>
<td>Post Marketing Safety Reports</td>
<td></td>
<td></td>
</tr>
<tr>
<td>46</td>
<td>CD/Softcopy of dossier (including research papers and economic models if any)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>47</td>
<td>Sample of drug (one unit only with packaging/ box) if requested</td>
<td></td>
<td></td>
</tr>
<tr>
<td>48</td>
<td>List of references in Vancouver style</td>
<td></td>
<td></td>
</tr>
<tr>
<td>49</td>
<td>Relevant treatment guidelines if available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>Payment Information:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bank draft/ money order/postal order made payable to ‘KETUA SETIAUSAHA, KEMENTERIAN KESIHATAN MALAYSIA’.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(          ) RM 5,000.00 [Proposal to list new medicine(s) into the MOH Medicines Formulary]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(          ) RM 3,000.00 [Proposal to list new indication(s) for existing medicines in the formulary list]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bank draft no./money order no./postal order no.: __________________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please refer to the guideline for details of the fee.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Filled in by / Date : 

NOTE: Incomplete applications will not be processed.

FOR OFFICE USE ONLY (SECRETARIAT)

<table>
<thead>
<tr>
<th>Date received</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration number</td>
<td></td>
</tr>
</tbody>
</table>

Checked by :
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.

<table>
<thead>
<tr>
<th>A. MEDICINE PARTICULARS</th>
</tr>
</thead>
</table>
| 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 trade name of the medicine registered in Malaysia. |
| 3 | Registration Holder | State the company name and address. |
| 4 | Manufacturer | State the company name and address. |
| 5 | DCA Registration No. | State the DCA Registration number and registration date.  
(Attach the DCA Approval Letter/ Latest certificate of renewal with full indication).  
*DCA: Drug Control Authority. |
| 6 | i) Approved Indication(S) | DCA Approved Indication(s):  
List all the DCA approved indication(s) of the medicines.  
To obtain certified document from the DCA.  
Indication(s) in MOHMF:  
State current indication(s) listed in MOHMF. |
| | ii) Restrictions of Use (if any) | 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. |
### Declaration of Products Containing Animal Sources

State the origins of the ingredients used in preparing the medicines.

### B. CLINICAL AND PHARMACOLOGICAL INFORMATION

#### 1. Dosing and Administration (dose, frequency, route of administration)

- **State the dose frequency and route of administration for the medicine in all population groups for each indication.**

  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

- **State the recommended duration of treatment and treatment cycle (if any).**
  - State 'life-long' if the medicine will be used continuously by patient.

#### 3. Other Relevant Information (if any)

### 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).**
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:

<table>
<thead>
<tr>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has therapeutic advantage over an existing medicine(s).</td>
</tr>
<tr>
<td>A cheaper alternative to an existing medicine(s).</td>
</tr>
<tr>
<td>Insufficiently treated condition.</td>
</tr>
<tr>
<td>Improve compliance.</td>
</tr>
<tr>
<td>New innovation medicine.</td>
</tr>
<tr>
<td>Others (specify below):</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>4a. MEDICINE AND TREATMENT RELATED COSTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>
### Guidelines for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary

| 4 | Total Medicine Cost Per Patient Per Year \( (d) \)  
\[ d = a \times b \times c \] | 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. | 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.  
If no published data is available, estimates can be used. However, estimates need to be justified. |
| 6 | Total Annual Cost Per Patient \( (f) \) | \[ f = (d + e) \] |

#### 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.

<table>
<thead>
<tr>
<th>STATEMENT OF DECLARATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>I, the undersigned, declare herewith that to my best knowledge and professional responsibility all information submitted within this dossier is complete and correct.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature: ……………………………</th>
<th>Date: ……………………………</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Officer: ……………………………</td>
<td>Contact Number: ……………………</td>
</tr>
<tr>
<td>Designation: ……………………………</td>
<td>Email Address: ………………………</td>
</tr>
<tr>
<td>Company’s Stamp:</td>
<td>Company Address:</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>MEDICINE NAME:</th>
<th>COMPANY NAME:</th>
</tr>
</thead>
<tbody>
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<table>
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<tbody>
<tr>
<td>1.</td>
<td>Generic name: Proposed dosage form(s) &amp; strength(s)/concentration(s)</td>
<td></td>
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<td>2.</td>
<td>Currently available dosage form(s) &amp; strength(s)/concentration(s) in MOHMF</td>
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<td>Proprietary name</td>
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<td>DCA Registration No.</td>
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<td>7.</td>
<td>i) Approved indication(s)</td>
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<td>7.</td>
<td>ii) Restrictions of use (if any)</td>
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<tr>
<td>8.</td>
<td>DCA approval letter/ Certificate of renewal</td>
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<tr>
<td>9.</td>
<td>DCA approved product information leaflet</td>
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<td>10.</td>
<td>Restrictions of use</td>
<td></td>
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<td>11.</td>
<td>Formulary/ Reimbursements in other countries with supporting documents</td>
<td></td>
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<tr>
<td>12.</td>
<td>Dosing and administration (including subpopulation doses)</td>
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<td>Device requirement</td>
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<td>Supply of device</td>
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<td>16.</td>
<td>Overview of disease</td>
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<td>17.</td>
<td>Rationale for listing application</td>
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<td>18.</td>
<td>Further elaboration on rationale for listing application</td>
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<td>Evidence tables for the above for each research paper</td>
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<td>Total annual cost per patient</td>
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<td>Price Declaration Form (Appendix 3)</td>
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<td></td>
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<td>Economic evaluations/ reports (if any)</td>
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<td>Evidence tables of PE studies /format in reporting economic evaluations (if any)</td>
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<td>33.</td>
<td>Budget implications</td>
<td></td>
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<tr>
<td>34.</td>
<td>Financial implication of proposed drug vs. comparator/ current management</td>
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<tr>
<td>35.</td>
<td>Signature, stamp and contact details of the proposer</td>
<td></td>
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<tr>
<td>36.</td>
<td>Post Marketing Safety Reports</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37.</td>
<td>CD/Softcopy of dossier (including research papers and economic models if any)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>38.</td>
<td>Sample of drug (one unit only with packaging/ box)</td>
<td></td>
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</tr>
<tr>
<td>39.</td>
<td>List of references in Vancouver style</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40.</td>
<td>Relevant treatment guidelines (if available)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Please provide reasons if the particulars are not submitted/ filled**
### Guidelines for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary

<table>
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<th>NO</th>
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</thead>
<tbody>
<tr>
<td>41</td>
<td>Payment Information:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bank draft/ money order/postal order made payable to ‘KETUA SETIAUSAHA, KEMENTERIAN KESIHATAN MALAYSIA’.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(   ) RM 2,000.00 [Proposal to add or amend formulation/dosage form/strength of medicines listed in the MOH Medicines Formulary]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bank draft no./money order no./postal order no.: ____________________________________</td>
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<tr>
<td></td>
<td>Please refer to the guideline for details of the fee.</td>
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</tbody>
</table>

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 (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.

<table>
<thead>
<tr>
<th>A. MEDICINE PARTICULARS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Generic Name [specify pharmaceutical form(s) &amp; strength(s)/concentration(s)]</td>
<td>Provide full generic name as available in MOHMF. Provide MDC code for easy identification of the medicine.</td>
</tr>
<tr>
<td>MDC Code</td>
<td></td>
</tr>
<tr>
<td>2 Indication(s) as in MOH Medicines Formulary</td>
<td>State the corresponding indication(s) of the medicine proposed to be changed category of prescriber in MOHMF.</td>
</tr>
<tr>
<td>3 Currently Available Brands and Manufacturer</td>
<td>State the brand name of the medicine and the manufacturer. For non-patented medicine state the generics that are available.</td>
</tr>
<tr>
<td>4 Restrictions of Use (if any)</td>
<td>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.</td>
</tr>
<tr>
<td>5 Category of Prescriber</td>
<td>Existing category of prescriber in MOHMF: Proposed category of prescriber:</td>
</tr>
<tr>
<td>6 Existing Medicines in the Proposed Category of Prescriber</td>
<td>State the alternatives in the MOHMF with the same indication and proposed category of prescriber.</td>
</tr>
<tr>
<td>7 Is the Medicine a Replacement for Existing Alternative in MOHMF?</td>
<td>Yes: ................................. (Suggest medicine(s) that can be replaced, fill in Form D5)</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>
# Guidelines for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary

## The Main Reason(s) for this Proposal

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).

## B. CLINICAL AND PHARMACOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th></th>
<th>Dosing and Administration (Dose, Frequency)</th>
<th>State the dose and frequency for the medicine in all population groups for each indication.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adult Dose</td>
<td></td>
</tr>
<tr>
<td>1a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1b</td>
<td>Paediatric Dose (if applicable)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Course of Treatment (Duration) and Repeats if any</td>
<td>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.</td>
</tr>
<tr>
<td>3</td>
<td>Concomitant Therapies (If any)</td>
<td>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.</td>
</tr>
<tr>
<td>4</td>
<td>Co-administered Therapies to Manage Side-Effects</td>
<td>If the use of this medicine results in the need for co-administration of other therapies to manage the side-effects of the applied medicine, state these additional therapies (with dosage, frequency and duration)</td>
</tr>
</tbody>
</table>
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. 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/effectiveness 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

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Price Per Unit (RM): <em>(a)</em></td>
<td>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).</td>
</tr>
<tr>
<td>2</td>
<td>Number of Dosage Units Administered Per Day or Per Cycle <em>(b)</em></td>
<td>State the number (or average number) of dosage units administered per day or per cycle.</td>
</tr>
<tr>
<td>3</td>
<td>Average Duration of Treatment in Days or Cycles Per Year <em>(c)</em></td>
<td>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.</td>
</tr>
<tr>
<td>4</td>
<td>Total Medicine Cost Per Patient Per Year <em>(d)</em></td>
<td>This can be calculated by multiplying <em>a</em>, <em>b</em> and <em>c</em></td>
</tr>
<tr>
<td></td>
<td><em>d = a x b x c</em></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Additional Cost Per Patient Per Year <em>(e)</em></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Data sources not limited to the MOH facilities (eg MOHE, MOD or private setting). Data sources must be reported.</td>
<td>If no published data is available, estimates can be used. However, estimates need to be justified.</td>
</tr>
<tr>
<td>6</td>
<td>Total Annual Cost Per Patient <em>(f)</em></td>
<td><em>f = (d + e)</em></td>
</tr>
</tbody>
</table>

Guidelines for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary
7. Total Procurement Last Year (institution) if any

<table>
<thead>
<tr>
<th>Year: ..................</th>
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<tbody>
<tr>
<td>RM ...................</td>
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</table>

8. Expected Number of Patients Per Year (institution)

State the expected number of patients (in your institution) to be on the medicine when prescriber category is changed.

9. Expected New Expenditure that will be Incurred for the Applied Medicine Per Year (institution)

State the expected expenditure (in your institution) that will be incurred (on the medicine) when prescriber category is changed.

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

<table>
<thead>
<tr>
<th>STATEMENT OF DECLARATION</th>
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</thead>
<tbody>
<tr>
<td>I, the undersigned, declare herewith that to my best knowledge and professional responsibility all information submitted within this dossier is complete and correct.</td>
</tr>
</tbody>
</table>

Signature: .....................  Date: .....................
Name of Officer: .....................  Contact Number: .....................
Designation: .....................  Email Address: .....................

Official Stamp:

Medicine name: ..............................................

Guidelines for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary 37
### 5. HEAD OF DEPARTMENT

<table>
<thead>
<tr>
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Comment: ………………………………………………………………………………………………….
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Signature: ............................... Date: ..............................
Name & Stamp: ..............................

### 6. HEAD OF PHARMACY DEPARTMENT

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Comment: ………………………………………………………………………………………………….
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Signature: ............................... Date: ..............................
Name & Stamp: ..............................

### 7. HEAD OF INSTITUTION

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Comment: ………………………………………………………………………………………………….
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Signature: ............................... Date: ..............................
Name & Stamp: ..............................
### 8. CHAIRMAN OF STATE DRUGS & THERAPEUTIC COMMITTEE

**[where applicable]**

<table>
<thead>
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Comment:  

| Comment: |  |
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Signature:  

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<th>Signature:</th>
<th>Date:</th>
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</table>

Name & Stamp:  

| 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**

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<td>1.</td>
<td>Generic name and MDC code</td>
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<td>Indication(s) as in MOH Medicines Formulary</td>
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<td>7.</td>
<td>The main reason(s) to change prescriber category</td>
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Guidelines for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary
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<td>24</td>
<td>Total annual cost per patient</td>
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<tr>
<td>25</td>
<td>Total procurement last year (institution) if any</td>
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<td>Expected new expenditure that will be incurred for the applied medicine per year (institution)</td>
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<td>29</td>
<td>Economic evaluations/ reports (if any)</td>
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<td></td>
</tr>
<tr>
<td>30</td>
<td>Evidence Tables of PE studies /format in reporting economic evaluations (if any)</td>
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<td></td>
</tr>
<tr>
<td>31</td>
<td>Statement of Declaration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>Signature, stamp and contact details of the proposer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>CD/Softcopy of dossier (including research papers and economic models if any)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>List of references in Vancouver style</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>Relevant treatment guidelines (if any)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Filled in by / Date:

NOTE: Incomplete applications will not be processed.

FOR OFFICE USE ONLY (SECRETARIAT)

<table>
<thead>
<tr>
<th>Date received</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration number</td>
<td></td>
</tr>
<tr>
<td>Checked by</td>
<td></td>
</tr>
</tbody>
</table>
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’s 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)

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

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Estimated number of patients per year (a)</td>
</tr>
<tr>
<td>2</td>
<td>Price per pack size (RM)</td>
</tr>
<tr>
<td>3</td>
<td>Dosing, frequency and duration of treatment</td>
</tr>
<tr>
<td>4</td>
<td>Total medicine cost per patient per year (b)</td>
</tr>
<tr>
<td>5</td>
<td>Estimated total cost of medicine incurred per year (a x b)</td>
</tr>
<tr>
<td>6</td>
<td>Available budget for the relevant discipline/activity</td>
</tr>
</tbody>
</table>

1. (for therapeutic discipline 1)
2. (for therapeutic discipline 2)

State the SKU and the medicine costs per SKU unit agreed for MOHMF.

Refer to sec. A

### C. 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:
<table>
<thead>
<tr>
<th>Medicine Name: …………………………………………</th>
</tr>
</thead>
</table>

### D. HEAD OF DEPARTMENT

<table>
<thead>
<tr>
<th>SUPPORT</th>
<th>NOT SUPPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Comment:** ……………………………………………………………………………………………………

………………………………………………………………………………………………………………

**Signature:** …………………………………  **Date:** …………………………

**Name & Stamp:** ……………………………

### E. HEAD OF PHARMACY DEPARTMENT

<table>
<thead>
<tr>
<th>SUPPORT</th>
<th>NOT SUPPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Comment:** ……………………………………………………………………………………………………

………………………………………………………………………………………………………………

**Signature:** …………………………………  **Date:** …………………………

**Name & Stamp:** ……………………………

### F. APPROVAL BY THERAPEUTIC & DRUGS COMMITTEE

<table>
<thead>
<tr>
<th>APPROVE</th>
<th>NOT APPROVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>MEDICINE</th>
<th>SPECIFIC INDICATION ONLY</th>
</tr>
</thead>
</table>

*Tick in the appropriate box*

### A. MEDICINE PARTICULARS

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Generic Name</td>
<td>Provide full generic name as available in MOHMF.</td>
</tr>
<tr>
<td></td>
<td>[specify dosage form(s) &amp; strength(s)/ concentration(s)]</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Malaysian Drug Code</td>
<td>Provide the MDC of the medicine as in the MOHMF.</td>
</tr>
<tr>
<td>3</td>
<td>Indication(s) to be Deleted</td>
<td>Specify the indication in MOHMF to be deleted or state all the indications if the medicine is to be deleted</td>
</tr>
<tr>
<td>4</td>
<td>Category of Prescriber</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Is this Medicine or Indication used by other Discipline?</td>
<td>NO: YES: State the discipline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NO: YES: State the discipline</td>
</tr>
<tr>
<td>6</td>
<td>Other Relevant Information (if any)</td>
<td></td>
</tr>
</tbody>
</table>

### B. RATIONALE FOR DELETION

*Include any supporting documents (if any)*
C. ALTERNATIVES MEDICINES FOR THE SAME/ SIMILAR INDICATION

<table>
<thead>
<tr>
<th></th>
<th>Other Medicine(s) for the Same Indications</th>
<th>Generic name 1: .......................................................</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>MDC Code/ATC: .......................................................</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Generic name 2: .......................................................</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MDC Code/ATC: .......................................................</td>
</tr>
</tbody>
</table>

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

I, the undersigned, declare herewith that to my best knowledge and professional responsibility all information submitted within this dossier is complete and correct.

Medicine Name: .......................................................  
Signature: .......................................................  
Date: .......................................................  
Name of Officer: .......................................................  
Contact Number: .......................................................  
Designation: .......................................................  
Email Address: .......................................................  
Official Stamp: .......................................................  
Address: .......................................................
Medicine Name: .............................................

<table>
<thead>
<tr>
<th>F. HEAD OF DEPARTMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUPPORT</td>
</tr>
<tr>
<td>Comment:</td>
</tr>
<tr>
<td>Signature:            Date:</td>
</tr>
<tr>
<td>Name &amp; Stamp:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>G. HEAD OF PHARMACY DEPARTMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>[for application from MOH Institution]</td>
</tr>
<tr>
<td>SUPPORT</td>
</tr>
<tr>
<td>Comment:</td>
</tr>
<tr>
<td>Signature:            Date:</td>
</tr>
<tr>
<td>Name &amp; Stamp:</td>
</tr>
</tbody>
</table>
Guidelines for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary

Medicine Name: ......................................................

### H. HEAD OF INSTITUTION

(for application from MOH Institution)

<table>
<thead>
<tr>
<th>SUPPORT</th>
<th>NOT SUPPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comment: ........................................................................................................................................
........................................................................................................................................

Signature: .............................................. Date: ..........................................

Name & Stamp: ........................................

### I. CHAIRMAN OF STATE DRUGS & THERAPEUTIC COMMITTEE

(where applicable)

<table>
<thead>
<tr>
<th>SUPPORT</th>
<th>NOT SUPPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comment: ........................................................................................................................................
........................................................................................................................................

Signature: .............................................. Date: ..........................................

Name & Stamp: ........................................

NOTE: Incomplete application will not be processed.

### FOR OFFICE USE ONLY (SECRETARIAT)

<table>
<thead>
<tr>
<th>Date received</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Registration number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Checked by</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
APPENDICES

APPENDIX 1: LETTER OF INTENT FORMAT

Company/ Institution letter head

Date:

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

<table>
<thead>
<tr>
<th>NO.</th>
<th>CRITERIA</th>
<th>YES/NO</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medicines Must be Registered With The Drug Control Authority (DCA) in Malaysia For at Least 12 Months.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Indications Must be Approved by The DCA in Malaysia.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>The Medicine (and its Indication(s) Applied for Listing) is Listed in The Reimbursement List / National Formulary in at Least Two Countries.*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Single Chemical Entity Must be Listed First in The MOHMF before The Application of Listing for The Fixed Dose Combination of Finished Pharmaceutical Product.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Medicines Must Have Therapeutic Advantage Supported by Scientific Evidences.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th></th>
<th>Medicine Name &amp; Strength</th>
<th>Proprietary Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Registration holder &amp; Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>i) DCA Approved Indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>ii) Proposed Indication(s) for the MOH Medicines Formulary</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>iii) Restrictions of Use (if any)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

### B. EXPERT OPINION

<table>
<thead>
<tr>
<th></th>
<th>Experience of using this medicine:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Hospital/Institution:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Duration of use:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Comment:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Efficacy in comparison with standard medicine treatment and/or current available medicine(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>More effective</th>
<th>Effective</th>
<th>Less effective</th>
<th>Limited efficacy</th>
<th>Similar efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Name the current standard treatment:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Comment:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Base on your experience/opinion, do you think this medicine should be listed in MOH Medicines Formulary?</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Reasons:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>What is the percentage of your patient suitable for the medicine?</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>
### 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:  

---

*Guidelines for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary*
### APPENDIX 3: MEDICINE PRICE DECLARATION FORM

<table>
<thead>
<tr>
<th>MEDECINE PRICING DETAILS</th>
<th>For Secretariat Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Type of Dossier</td>
</tr>
<tr>
<td>2</td>
<td>Generic Name [specify dosage form(s) &amp; strength(s)/ concentration (s)]</td>
</tr>
<tr>
<td>3</td>
<td>Proprietary Name</td>
</tr>
<tr>
<td>4</td>
<td>Product Registration Holder</td>
</tr>
<tr>
<td>5</td>
<td>Manufacturer &amp; Country of Origin</td>
</tr>
<tr>
<td>6</td>
<td>Packaging Size</td>
</tr>
<tr>
<td>7</td>
<td>Price Per Packaging (RM) (Inclusive of 0.4% e-Perolehan Fee)</td>
</tr>
<tr>
<td>8</td>
<td>Price Per Unit (RM) (Inclusive of 0.4% e-Perolehan Fee)</td>
</tr>
<tr>
<td>9</td>
<td>Public Wholesale Price per unit (RM) in TWO in ASEAN countries</td>
</tr>
<tr>
<td>10</td>
<td>Public Wholesale Price per unit (RM) in TWO *peer / * similar economic status Countries from Other Region</td>
</tr>
<tr>
<td>11</td>
<td>Public Wholesale Price per unit (RM) in Country of Origin</td>
</tr>
<tr>
<td>12</td>
<td>Patent validity date</td>
</tr>
</tbody>
</table>

### 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) year from the date of the circular on the 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, Pharmaceutical Service Division.

3. Any offers for patient assisted programme should be explicitly declared and detailed.
## APPENDIX 4: EVIDENCE TABLE (EFFICACY/EFFECTIVENESS AND SAFETY)

<table>
<thead>
<tr>
<th>Bibliography / Citations</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Design</td>
<td></td>
</tr>
<tr>
<td>Level of Evidence</td>
<td></td>
</tr>
<tr>
<td>Number of patients and patients’ characteristics</td>
<td></td>
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<tr>
<td>Intervention</td>
<td></td>
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<tr>
<td>Comparison/ control</td>
<td></td>
</tr>
<tr>
<td>Length of follow-up (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Outcome measures/ effect size</td>
<td></td>
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</tbody>
</table>
### APPENDIX 5: LEVEL OF EVIDENCE

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
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<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1 -</td>
<td>Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>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</td>
</tr>
<tr>
<td>2+</td>
<td>Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2 -</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
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<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
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<tr>
<td>4</td>
<td>Expert opinion</td>
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</table>

(Source: Scottish Intercollegiate Guidelines Network)
## APPENDIX 6: EVIDENCE TABLE (REPORTING ECONOMIC EVALUATIONS)

<table>
<thead>
<tr>
<th>Title</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Abstract</td>
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<tr>
<td><strong>Introduction</strong></td>
<td></td>
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<tr>
<td>Background and objectives</td>
<td></td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
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<tr>
<td>Target population and subgroups</td>
<td></td>
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<tr>
<td>Setting and location</td>
<td></td>
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<tr>
<td>Study Perspective</td>
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<tr>
<td>Comparators</td>
<td></td>
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<tr>
<td>Time horizon</td>
<td></td>
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<tr>
<td>Discount rate</td>
<td></td>
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<tr>
<td>Choice of health outcomes</td>
<td></td>
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<tr>
<td>Measurement of effectiveness</td>
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<tr>
<td>Measurement and valuation of preference based outcomes (if applicable)</td>
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<tr>
<td>Estimating resources and costs</td>
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<tr>
<td>Currency, price date, and conversion</td>
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<tr>
<td>Choice of model</td>
<td></td>
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<td>---------------------------------------------------</td>
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<tr>
<td>Assumptions</td>
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<tr>
<td>Analytical methods</td>
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</table>

**Results**

<table>
<thead>
<tr>
<th>Study Parameters</th>
<th></th>
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<tbody>
<tr>
<td>Incremental costs and outcomes</td>
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</tr>
<tr>
<td>Characterising uncertainty</td>
<td></td>
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<tr>
<td>Characterising heterogeneity</td>
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</table>

**Discussion**

<table>
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<tr>
<th>Study findings, limitations, generalisability, and current knowledge</th>
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</thead>
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**Other**

<table>
<thead>
<tr>
<th>Source of funding</th>
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</thead>
<tbody>
<tr>
<td>Conflict of interest</td>
<td></td>
</tr>
</tbody>
</table>

APPENDIX 7: WORKFLOW OF APPLICATION OF DOSSIER D3 & D5 BY MOH INSTITUTIONS

Consultants/ Specialists/Medical Officers/ Dentists/ Pharmacists*

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

Institution DTC

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

State DTC*

Evaluation of dossier and consideration for submission to MOHMF Secretariat.

MOHMF Secretariat


MOHMF Panel

Decision for listing into MOHMF

List into MOHMF

File documents

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

Note:
* where applicable

Consultants/ Specialists/ Medical Officers/ Dentists/ Pharmacists*
Institution DTC
Not supported

Not supported

Not supported

Letter to applicant

Letter to applicant

Letter to applicant

Letter to applicant

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Results

Approval

Not supported

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