Updates for Dossier Submission: Key Changes in the 3rd Edition for Listing Medicines with the Malaysia Ministry of Health

Summary of Changes

Table of contents

Summary of changes

No.	Item	Change
1	**Listing workflow**	Updates on duration of each processing stage
2	**Type of dossier forms**	Changes in types of dossier forms
3	**Email and mailing address**	Changes in address
4	**Intention to submit**	New instructions
5	**Dossier formatting**	Additional instructions
6	**Dossier arrangement (hardcopy)**	New instructions
7	**Submission format (hardcopy vs. softcopy)**	New instructions
8	**Dossier D1 checklist and Dossier D1 form**	Changes in contents
9	**Dossier D2 checklist and Dossier D2 form**	Changes in contents
10	**Medicine price declaration form**	No changes in content
11	**Application statement of declaration**	Additional clauses
12	**Supporting clinical evidence**	No changes
13	**Supporting economic evidence**	No changes
14	**Provision of one-year utilisation data post-listing**	New requirement
15	**Appendix: Workflow**	Updates on duration of each processing stage

Listing workflow

Updates on the duration of each processing stage

- Specific timelines for each processing stage have been updated in the 3rd edition of the Guideline.
- Below is a comparison between the 2nd and the 3rd edition of the Guideline. Refer **Appendix: Workflow** for work process flowchart.

	2ND EDITION OF THE GUIDELINE	3RD EDITION OF THE GUIDELINE
Dossier completeness screening timeline	Not explicitly stated	Screening for completeness of document to be completed **within seven days** of receiving documents from PRH
BIA screening timeline	Not explicitly stated	Screening set at **90 working days, excluding stop clock** for obtaining feedbacks from stakeholders and applicant. A **maximum of three correspondence** is allowed during screening • If BIA/CE is not satisfactory, a post submission meeting may be offered to discuss the issues involved • However, the dossier will be considered incomplete and will be rejected by the Secretariat if it is still not satisfactory • The applicant may need to resubmit the dossier after cooling-off period of three months along with previous comments and changes in the model
Payment timeline	Payment to be made upon dossier submission	Payment to be made **within 15 working days after date of screening approval** (completeness of document and completion of BIA screening) Official receipt will be issued within five working days
Dossier evaluation timeline	Evaluation will be performed and completed within 120 calendar days.	Upon confirmation of payment, dossier shall be evaluated and completed **within 90 working days**
Outcome of MOHMF Review Panel Meeting	PRH to be notified on outcome within 15 working days	PRH to be notified on outcome **within three working days**
List of notifications to PRH	Not explicitly stated	• Acceptance of dossier • BIA screening start date (for Dossier D1) • Screening approval and payment instruction (applicable for submission by PRH) • Official payment receipt and evaluation notification • Completion of dossier evaluation • Presentation of dossier in the MOHMF panel meeting (within 30 days before the meeting) • Decision of the MOHMF panel (within three working days from the date of meeting)

Abbreviations: BIA, Budget Impact Analysis; CE, Cost-effectiveness; MOHMF, Ministry of Health Medicines Formulary; PRH, Product registration holder

Types of dossier forms

Changes in types of dossier forms

- The 3rd edition of the Guideline contains only **four** types of dossier forms, as opposed to the 2nd edition of the Guideline, which has five.
- Below is a comparison between the 2nd and the 3rd edition of the Guideline.

FORM	2ND EDITION OF THE GUIDELINE	3RD EDITION OF THE GUIDELINE
D1	• To list new medicines into MOHMF or to list new indication for existing medicines by PRH only • One indication per dossier	• To list new medicines into MOHMF or to list new indication by **PRH, DWC** and MOH**** • One medicine or indication per dossier • If >1 indication for one medicine, separate dossier required (Refer to pg. 71 of the Guideline)
D2	• To add dosage form/strength listed in MOHMF by PRH only	• To add dosage form/strength listed in MOHMF by **PRH, DWC** and MOH****
D3	• To change category of prescriber by MOH only	• No changes
D4	• To list new medicines into institution's medicines formulary by MOH only	• To **delist** approved medicine or indication from MOHMF by MOH only • **PRH can no longer submit** (see pg. 69 of Guideline)
D5	• To delist approved medicine or indication from MOHMF by PRH or MOH	• Refer D4 for delisting • **D5 no longer applicable**

Abbreviations: DWC, Drug Working Committee; MOH, Ministry of Health; MOHMF, Ministry of Health Medicines Formulary; PRH, Product registration holder

**MOH DWC & other programme/division in MOH are allowed to submit these types of dossiers for multisource medicines only.

Multisource medicines refer to pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable

Email and mailing address

Changes in address

- The email address and mailing address of the Secretariat have been updated. Please refer to the table below.

2ND EDITION OF THE GUIDELINE	3RD EDITION OF THE GUIDELINE
sekretariatfukkm@moh.gov.my Secretariat MOH Medicines Formulary Review Panel Pharmacy Practice and Development Division Ministry of Health Malaysia Lot 36, Jalan Universiti 46200 Petaling Jaya, Selangor	**cpfor@moh.gov.my** Secretariat MOH Medicines Formulary Pharmacy Practice and Development Division Ministry of Health Malaysia Lot 36, Jalan Profesor Diraja Ungku Aziz 46200 Petaling Jaya, Selangor

Intention to submit

New instructions

- The list of eligibility criteria in the Letter of Intention (LOI) has been reduced to **five** in the 3rd Edition of the Guideline. Below is a comparison between the 2nd and the 3rd edition of the Guideline.

2ND EDITION OF THE GUIDELINE (PAGE 53)	
No	**Criteria**
1.	Medicine (new chemical entity) must be registered with the Drug Control Authority (DCA) in Malaysia for at least 12 months
2.	Indication(s) must be approved by the DCA in Malaysia
3.	The medicine (and its indication(s) applied for listing) is listed in the reimbursement list / national formulary in at least two (2) countries
4.	Single chemical entity must be listed first in the MOHMF before the application of listing for the fixed dose combination of finished pharmaceutical product • *Please provide valid justification if this criteria is not fulfilled* *Note: This criteria has been removed from the list in the LOI*
5.	Medicine must have been used for at least 6 months in Malaysia post DCA registration: • *An updated Periodic Safety Update Report (PSUR) or Periodic Beneft Risk Evaluation Report (PBRER) must be made available. Local safety report is preferred* • *The usage after registration shall be supported with sales report*
6.	Medicine must have therapeutic advantage supported by scientific evidence • *Comparative effectiveness and safety to the current standard practice evidences with head-to-head studies are highly preferred*

3RD EDITION OF THE GUIDELINE (PAGE 33)	
No	**Criteria**
1.	Medicine (new chemical entity) must be registered with the Drug Control Authority (DCA) in Malaysia for at least 12 months *Note: Only applicable for dossier D1 (new medicine)*
2.	Indication(s) must be approved by the DCA in Malaysia
3.	The medicine (and its indication(s) applied for listing) is listed in the reimbursement list / national formulary in at least two (2) countries *State the country referenced (any country) and provide supporting evidence (URL/snapshot/ document of reimbursement containing information on generic name, indication and approval – in English/translated into English*
4.	Medicine must have been used for at least 6 months in Malaysia post DCA registration: Please provide the following documents: • *Sales report for six months - (Example: summary of sales which contains information on date for first sale, quantity for public and private sectors without stating the name of facilities involved)* • *Executive summary of updated Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER) (Local safety report is preferred)*
5.	Medicine must have therapeutic and/or safety advantage supported by scientific evidence *Please provide summary and citation (Vancouver style) of the comparative effectiveness and/or safety studies. Head-to-head studies are highly preferred*

Abbreviations: DCA, Drug Control Authority, MOHMF, Ministry of Health Medicines Formulary

- However, the **requirement for fixed-dose combination (FDC) is still enforced** in the 3rd Edition of the Guideline. Instead of being included in the list of eligibility criteria, requirement for fixed dose-combination has relocated to statement 1.1.5 to 1.1.7 of its own in the 3rd Edition of the Guideline (See below; pg. 11 to 12).

LISTING OF FIXED DOSE COMBINATION

2nd edition: PRH to justify if this criterion is not fulfilled

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

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

a. D1 Dossier: If one or more of the active ingredients is not listed as single agent in MOHMF

b. D2 Dossier: If all the single active ingredient is listed in MOHMF and the proposed indication(s) of the FDC product is similar to the indication(s) listed for each of its active ingredient.

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

- **Additional clauses** have been added to the LOI (see Statement 2 below).

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

i. the company has to issue a six-month notice before any product withdrawal from the market.

ii. the company has to provide one year utilisation data post-listing

- **A scanned copy** of the signed LOI in PDF format and supporting documents **must be emailed** to **cpfor@moh.gov.my**. The following is the list of required supporting documents:
  - » URL/snapshot/document of national reimbursement/formulary in at least two countries
  - » Sales report/ evidence of usage for the recent six months
  - » Executive summary of updated Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER)
  - » Summary and citation (Vancouver style) of the comparative effectiveness and/or safety studies
- Detailed listing processes for D1, D2 and D3 dossier submission are found on pg. 11 to 13 of the 3rd edition of the Guideline.

Dossier formatting

Additional instructions

- Table below shows the updated formatting instruction in the 3rd edition of the Guideline.

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

- Some of the key changes are:
  - **No bold print** in dossier except for headings
  - **No scripted/italicised fonts**, except for scientific names or terms in other languages
- Detailed formatting instructions are found on pg. 28 of the 3rd edition of the Guideline.

Dossier arrangement (hardcopy)

New instructions

- The 3rd edition of the Guideline has new instructions on dossier arrangement.
- Table below is a comparison between the 2nd and the 3rd edition of the Guideline.

2ND EDITION OF THE GUIDELINE	3RD EDITION OF THE GUIDELINE
Page 1 – Cover with name of medicine, type of dossier, contact person (email and phone number) Page 2 – Dossier checklist Page 3 – Table of contents / Index table Page 4 onwards – Main dossier	a. Cover b. Table of contents c. Part A: Dossier forms » Dossier checklist » Dossier forms » Price declaration form (applicable for D1, D2, D3) » Cost comparison and financial implication (applicable for D2 and D3 only) » Statement of Declaration d. Part B: Supporting documents » Copy of LOA » Latest DCA approved Product information and DCA indication certificate (upon request only) » Supporting Clinical Evidence and Evidence table » Supporting Economic Evidence (i.e., Evidence table, BIA full report) » USB drive for softcopy of dossier (labelled with medicine names: generic and brand) e. Others: Sample product upon request only

Abbreviations: BIA, Budget Impact Analysis; DCA, Drug Control Authority; LOA, Letter of Acceptance

- Detailed instructions are found on pg. 28 to 29 of the 3rd edition of the Guideline.

Submission format (hardcopy vs. softcopy)

New instructions

- The 3rd edition of the Guideline has new instructions on dossier submission format.
- Table below is a comparison between the 2nd and the 3rd edition of the Guideline.

2ND EDITION OF THE GUIDELINE	3RD EDITION OF THE GUIDELINE
• Three duplicates of complete dossier form and one hardcopy of supporting document • Electronic copy of complete dossier and supporting document in USB or CD	**One hardcopy and softcopy (in USB) of:** a. Dossier checklist b. Dossier form c. Copy of LOA d. DCA-approved product information e. DCA indication certificate (upon request only) f. Full-text journal g. BIA report (PDF and editable Word) **Softcopy (in USB) only:** a. Guidelines b. BIA live excel sheet c. PSUR/PBRER full report

Abbreviations: BIA, Budget Impact Analysis; DCA, Drug Control Authority; LOA, Letter of Acceptance; PSUR, Periodic Safety Update Report; PBRER, Periodic Benefit Risk Evaluation Report

- Detailed instructions are found on pg. 29 of the Guideline.

Dossier D1 checklist and Dossier D1 form

Changes in contents

- The 3rd edition of the Guideline has updated the **Dossier D1 checklist** and **Dossier D1 form**. The major changes are listed below:
  - » **DCA indication certificate** to be attached **upon request only** (Note: in the 2nd edition of the Guideline, DCA indication certificate must be attached upon submission).
  - » In 2nd edition of the Guideline, Dossier D1 form has sections on supporting clinical evidence (Section 3), supporting economic evaluation (Section 4) and Applicant's Statement of Declaration. These sections have been removed from the Dossier D1 form of 3rd edition of the Guideline, to align with updated instructions on Dossier Arrangement.
- The new Dossier D1 checklist can be found on Appendix 3A of the 3rd edition of the Guideline (pg. 37 to 39), while Dossier D1 form is on the Appendix 3B (pg. 40 to 43).

Dossier D2 checklist and Dossier D2 form

Changes in contents

- The 3rd edition of the Guideline has updated the **Dossier D2 checklist** and **Dossier D2 form.** The major changes are listed below:
  - » In 2nd edition of the Guideline, Dossier D2 form has a section on Medicine and Treatment related cost. This section has been removed from Dossier 2 form of the 3rd edition of the Guideline. Details on costs of medicines and other costs related to the proposed treatment should be stated using the format in Appendix 7 of the 3rd edition of the Guideline (pg. 57).
  - » In 2nd edition of the Guideline, Dossier D2 form has sections on supporting clinical evidence (Section 3), supporting economic evaluation (Section 4) and Applicant's Statement of Declaration. These sections have been removed from the Dossier D2 form of 3rd edition of the Guideline, to align with updated instructions on Dossier Arrangement.
- The new Dossier D2 checklist can be found on Appendix 4A of the 3rd edition of the Guideline (pg. 44 to 46), while Dossier D2 form is on the Appendix 4B (pg. 47 to 50).

Medicine price declaration form

No changes in content

- The Medicine Price Declaration Form is found in Appendix 6 of the 3rd edition of the Guideline (pg. 56).

Applicant statement of declaration

Additional clauses

- **Additional clauses (bolded below)** have been added into the Statement of Declaration form:

STATEMENT OF DECLARATION

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

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

- The Applicant Statement of Declaration (Dossier D1 & D2) is found in Appendix 8A of the 3rd edition of the Guideline (pg. 58).

Supporting clinical evidence

No changes

- There are **no changes** in the requirements for supporting clinical evidence.
- The following is the list of required supporting clinical evidence:
  - » Evidence of systematic search
  - » Evidence table
  - » Journal articles/written evidence (provide at least five for D1 and three for D2)
- Supporting clinical evidence was Section 3 of the D1 and D2 dossier forms in the 2nd edition of the Guideline. In the latest 3rd edition of the Guideline, supporting economic evidence will be a standalone appendix on its own i.e., Appendix 9 of the 3rd edition of the Guideline (pg. 61).

Supporting economic evidence

No changes

- There are **no changes** in the requirements for supporting economic evidence.
- The following is the list of required supporting economic evidence:
  - » Evidence of systematic search
  - » Evidence table
  - » Mandatory BIA i.e., a full report and a live Excel worksheet with 5-year horizon and from MOH perspective
- Supporting economic evidence was Section 4 of the D1 and D2 dossier forms in the 2nd edition of the Guideline. In the latest 3rd edition of the Guideline, supporting economic evidence will be a standalone appendix on its own i.e., Appendix 10 of the 3rd edition of Guideline (pg. 62 to 63).

Provision of one-year utilisation data post-listing

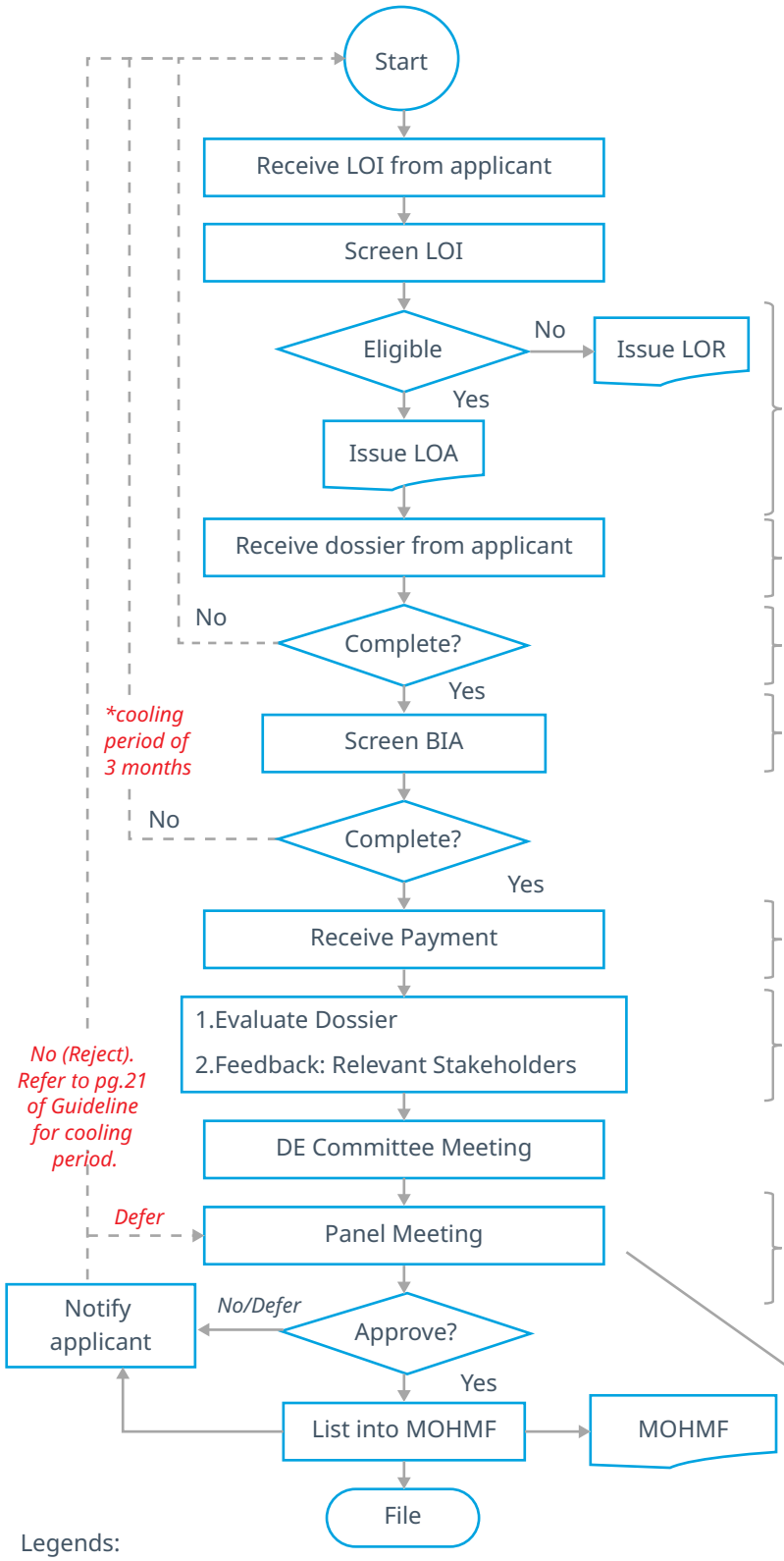
New requirement

- The applicant is required to provide **one-year utilisation data post-listing** for medicines newly listed into MOHMF.

Appendix: Workflow

Updates on duration of each processing stage

Workflow of listing medicine into the MOHMF (Dossiers D1)



5 working days
- PRH to receive LOA/LOR within 5 working days.
- PRH to submit complete dossier within 6 months from the date of LOA.

6 months
- Secretariat to screen completeness of dossier within 7 working days.

7 working days

90 working days
- Screening of BIA to complete within 90 working days. First correspondence to PRH is within 30 working days from BIA screening start date.

15 working days
- PRH to pay within 15 working days of completion of BIA screening. Secretariat to issue official receipt within 5 working days.

90 working days
- Evaluation of Dossier to complete within 90 days after payment received.

3 working days
- PRH to be notified on outcome within 3 working days.

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

Table 8: MOHMF panel meeting schedule

Meeting No.	Month
1	March
2	July
3	November

Note: Dates are subject to change

Legends:
LOI: Letter of Intent
LOR:Letter of Rejection
BIA:Budget Impact Analysis
DE:Drug Evaluation
D1:New medicine/Add new indication

Abbreviations: PRH, product registration holder; LOA, Letter of Acceptance; LOR, Letter of Rejection

List of abbreviations

Abbreviations	Definitions
BIA	Budget Impact Analysis
CEA	Cost-Effectiveness Analysis
DCA	Drug Control Authority
DWC	Drug Working Committee
FDC	Fixed-dose combination
LOA	Letter of Acceptance
LOI	Letter of Intention
LOR	Letter of Rejection
MOH	Ministry of Health
MOHMF	Ministry of Health Medicines Formulary
PBRER	Periodic Benefit Risk Evaluation Report
PPDD	Pharmacy Practice and Development Division
PRH	Product Registration Holder
PSUR	Periodic Safety Update Report

Glossary

TERMS	DEFINITIONS
Guideline	Guidelines on Submission of Dossier for Listing into the Ministry of Health Medicines Formulary will be referred to as the Guideline for the purposes of this document.
Secretariat	The Pharmacy Practice and Development Division (PPDD) acts as the Secretariat to the Ministry of Health Medicines Formulary (MOMHF) Panel and is responsible for processing the dossier submission. PPDD will be referred to as the Secretariat for the purposes of this document.
Multisource medicines	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Fixed-dose combination	A finished pharmaceutical product that contains two or more active ingredients in a single dosage form.

References

- 3rd Edition of MOHMF Guideline - https://pharmacy.moh.gov.my/sites/default/files/document-upload/gp-dossier-submission-3rd-ed-2024_0.pdf
- 2nd Edition MOHMF Guideline. However, this version is no longer available on the website. It has been updated with the 3rd edition

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