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

***(Company/ Institution letter head)***Date:

**Secretariat**

MOH Medicines Formulary

Pharmacy Practice and Development Division

Ministry of Health Malaysia

Lot 36, Jalan Profesor Diraja Ungku Aziz

46200 Petaling Jaya, Selangor

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

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

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

*(Note: \*where applicable)*

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

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

Thank you.

Yours sincerely,

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| NO. | CRITERIA | YES/NO | COMMENT | FOR SECRETARIAT USE |
|  | 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)* |  |  |  |
|  | Indication(s) must be approved by the DCA in Malaysia. |  |  |  |
|  | 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)* |  |  |  |
|  | 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)*
 |  |  |  |
|  | Medicine must have therapeutic and/or safety advantage supported by scientific evidence.*Please provide summary and citation (Vancouver style) of the comparative effectiveness and/or safety studies. Head-to-head studies are highly preferred.*  |  |  |  |

|  |
| --- |
| **FOR SECRETARIAT USE** |
| RECEIPT DATE |  | Comment: |
| SCREENING DATE |  |
| SCREENED BY |  |