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ANP/PASC/003/2018v1

**Pharmacy Practice & Development Division, Ministry of Health**

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| ***For Office Use [PASc Registration Number ……………./year]*** |
| **PATIENT ACCESS SCHEME (PASc) APPLICATION FORM****Complex Scheme (Financial-/ Performance-based Scheme)** |
| **Note:** Complete this application form for proposed complex schemes that comply with the standard PASc submission for complex scheme. *(Refer to Guidelines on Proposal Submission for Patient Access Scheme (PASc) Implementation in Ministry of Health, Malaysia for further information and guidance on completion*).PASc must be transparent, clinically robust, plausible (credible), practical and has no unreasonable incentives. It must be operationally manageable without unduly complex monitoring, disproportionate additional costs and will not cause unintended adverse consequences on the pattern of patient care. |
| **I) GENERAL INFORMATION** |
| *(Please tick )* |  | **New Application** |  |  **Renewal Application** |
| Please indicate the type of Complex Scheme proposed *(Please tick )*  |  | **Financial-based Scheme** |  |  **Performance-based Scheme** |
| **GENERIC NAME***(specify dosage form(s), strength(s)/ concentration(s)*  | *Provide full generic name of the medicine, with the dosage form(s), strength(s) and concentration(s) included in the PASc* |
| **PROPRIETARY NAME** | *State the trade name of the medicine registered in Malaysia*  |
| **MAL REGISTRATION NO.** | **MAL**  |
| **INDICATION(s)** | * *State the DCA indication*
* *State the proposed indication (new medicine for listing)*
* *State the MOHMF indication(s) (existing medicine in the MOHMF)*
 |
| *State future indication(s) to which the PASc may apply.* *(registered with the DCA)* |
| **CATEGORY OF MEDICINE PROPOSED FOR PASc** *(please tick)* |  **New Medicine for Listing into the MOHMF** |
|  **Existing Medicine in the MOHMF** |
| **SUGGESTED PASc START DATE** | *Insert anticipated effective date* |
| **DURATION OF PASc** |  |
| **EXISTING PASc IN MALAYSIA** *(if any)* |  |
| **EXISTING PASc IN OTHER COUNTRIES AND DESCRIBE THE SCHEME** *(if any)* |  |
| **PATENT EXPIRY DATE** *(medicines under patent protection)* |  |

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| **II) OPERATION OF THE SCHEME**  |
| ***Operational aim:*** *Transparent, clinically robust, plausible (credible), practical and no unreasonable incentives.* |
| **Rationale** | *Please describe the rationale for choosing complex scheme and not a simple scheme* |
| **Indication** | *Please indicate whether the proposed scheme will apply to all current and planned future indication(s) for all preparations, in all settings* |
| **Details of scheme operation**  | * *Please describe the prescribing setting (e.g. hospitals or clinics), ordering, supply route, delivery and financial flows of the proposed scheme. Please provide a flow diagram that shows how the scheme will operate.*
* *Please indicate whether the proposed scheme will apply only to a subgroup of patients. How is the subgroup defined? What is the inclusion and exclusion criteria which have been used to select patients and how are the criteria measured and why have these measures been chosen? Please describe each step of the proposed scheme’s operation. If the proposed scheme will introduce variation to the current care pathway (in a case of performance-based scheme). Kindly describe these changes.*
* *Does the scheme requires any additional resources compared to without scheme. If YES, please provide details*
* *Please describe any possible impact that the scheme may give on the choice of treatment available in MOH*
* *Kindly provide details of the duration of the proposed scheme and the justification*
* *There may be specific circumstances in which the applicant might change or withdraw the proposed PASc. Kindly describe these circumstances*
* *Please confirm the notice period that will be provided to PPSD due to withdrawal/ termination of the scheme*
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| **III) COST BURDEN TO MOH** |
| *Schemes should be consistent with existing MOH financial status. Cost burden to MOH due to schemes, should be declared* |
| **Financial aspects**  | *Outline the estimated costs across the MOH to implement and operate the scheme including :*1. ***Set up, implementation and operation cost*** *(e.g. developing local standard operating procedures, records, training of staffs, additional staffs needed, time required for managing stocks and time for rebate calculations).*

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|  | ***CALCULATION OF COSTS*** | ***SOURCE*** |
| *Development of Standard Operation procedures* |  |  |
| *Records* |  |  |
| *Staff training* |  |  |
| Other *(add more rows as necessary)* |  |  |
| ***Total implementation and operation costs*** |  |  |

1. ***Additional treatment-related costs*** *likely to be incurred by implementing the proposed scheme (e.g. monitoring tests, diagnostic tests, appointments with clinician).*

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|  | ***CALCULATION OF COSTS*** | ***SOURCE*** |
| *Monitoring tests* |  |  |
| *Diagnostic tests* |  |  |
| *Appointments with clinicians*  |  |  |
| *Others* *(add more rows as necessary)* |  |  |
| ***Total treatment-related costs*** |  |  |

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|  | * *Please explain in details how the benefits will be calculated (e.g. rebates calculation and payment). Who will be responsible for issuing the rebates or free stocks?*
* *Please describe any mechanisms included in the scheme that will minimise the possibility that MOH might be overlooked and not requesting/claim rebates or free stocks from company.*
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| **IV) POPULATION** |

 ***Priority:*** *Schemes that will deliver greatest benefits to patients (e.g. previous unmet need).*

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| Please provide the estimated number of patients who will be treated with the medicine over the stated duration (including new future indications).  |
| **Indication** | **Estimated Number of Patients** |
| ***Year 1*** | ***Year 2*** | ***Year 3*** | ***+Year 4*** |
| Number of populations covered by current indication  |  |  |  |  |
| *Number of patients eligible for treatment with this medicine* |  |  |  |  |
| *Number of patients to be treated with this medicine* |  |  |  |  |
| Expected market uptake (%)*Market share for current treatment mix (including the proposed medicine)* |  |  |  |  |
| Market shares of other drugs which will be affected by the uptake of this drug*Market shares for future treatment mix (including the proposed medicine)* |  |  |  |  |
| *†Source:* |  |  |  |  |

 † Information from Budget Impact Analysis submitted for listing of new medicine in the MOHMF can be used

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| **V) MONITORING OF THE SCHEME AND DATA COLLECTION** |
| ***Assessment aim:*** *It must be operationally manageable without unduly complex monitoring, no additional administrative burden, and will not cause unintended adverse consequences on the pattern of patient care.* |
| **Monitoring role and responsibilities**  | *Please define monitoring role and responsibilities for the applicant, institutions and other relevant parties.*  |
| **Scheme monitoring method**  | *Please describe how the scheme will be monitored. Kindly state plans for monitoring and attach documents which will be used for monitoring purposes. (e.g. number of vials, patient progress, safety monitoring with all relevant parameters, provision of free treatment record).* *Outline any additional data and/or parameters monitoring required as compared to situation without PASc.* |
| **Data collection**  | *MOH may require data from the scheme for reassessment purposes and to gain a better understanding of the impact of the scheme.* *(How will the data from the scheme be gathered, collated and analysed? Who will be responsible for this in making sure that data are readily available?)* |

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| **VI) BENEFITS OF THE SCHEME**  |
| Please use this section to explain to what extend does the medicine address a currently unmet need in the MOH and how this scheme will ensure that MOH will receive the financial benefits? |
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| **VII) ADDITIONAL INFORMATION**  |
| Please use this section to include any additional information that you believe is important for consideration by PPDD/PASc Panel in reviewing the proposed scheme |
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| **VIII) COMPANY CONTACT DETAILS** |
| **CONTACT DETAILS** | **Name** |  |
| **Designation** |  |
| **Address** |  |
| **Contact number** |  |
| **Email address** |  |