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GUIDELINE ON PROPOSAL SUBMISSION FOR PATIENT ACCESS SCHEME (PASc) IMPLEMENTATION IN MINISTRY OF HEALTH

Pharmacy Practice & Development Division
Ministry of Health, Malaysia

2018

Guideline on Proposal Submission for Patient Access Scheme (PASc) Implementation in Ministry of Health

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This document describes the process the Pharmacy Practice & Development Division, Ministry of Health uses to advise on the submission of Patient Access Scheme (PASc) proposal.

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CONTENTS

ABBREVIATIONS

Abbreviations:

DCA	Drug Control Authority
MOH	Ministry of Health
MOHMF	Ministry of Health Medicines Formulary
PASc	Patient Access Scheme
PPDD	Pharmacy Practice & Development Division

1.0 Introduction

Patient Access Scheme (PASc) is a scheme proposed by pharmaceutical companies and agreed upon by the Ministry of Health (MOH), Malaysia in order to improve access to medicines which are likely to have high budget impact either due to high treatment cost per patient and/or large volumes of use. This scheme involves innovative pricing agreements designed to improve cost effectiveness and facilitate patient access to specific medicines. This scheme may address the rising cost pressure, consumer demands and uncertainties, while attempting to provide patient access to innovative care within finite budgets.

This guideline set out the process for the submission, evaluation and approval of PASc in MOH health facilities. The main part of this guideline is written for pharmaceutical companies who intend to propose PASc for medicines to be used within MOH health facilities. These requirements are designed to standardise submissions by pharmaceutical companies and minimise variability in the quality of proposal submitted.

Scope of the guideline

The scope of the guideline includes procedures for:

a) PASc proposal with dossier submission for listing into the MOH Medicines Formulary (MOHMF)

b) PASc proposal for existing medicines in the MOHMF

An application with complete documents and accurate information will expedite the review process of a submission. It will also facilitate comprehensive assessment of the proposed PASc by the Pharmacy Practice and Development Division (PPDD) and consequently the decision-making process by the MOH PASc Review Panel (which will be referred to as the PASc Panel throughout this guideline). However, a complete application does not guarantee approval of a PASc by the MOH Controlling Officer.

This guideline shall be read in conjunction with the current laws and regulations together with other relevant legislations, where applicable, but not limited to the Guideline for Submission of Dossier for Listing into the Ministry of Health Medicines Formulary.
This guideline can be accessed online via www.pharmacy.gov.my

Agreed key principles for PASc can be found in ***Appendix 1***.

2.0 Types of Scheme

In general, PASc can be classified into two categories:

a) Financial-based Scheme

Financial-based scheme is a scheme that offers a rebate or free supply based on usage without linking to health outcomes (e.g. discounts or rebates, price-volume agreements, utilisation caps).

It can be further divided into:

i. Simple Scheme

Simple financial-based scheme which involves **fixed percentage discount** or a **fixed price agreement** is the preferred scheme within MOH facilities as it generally does not impose any significant burden to either MOH or pharmaceutical companies.

ii. ***Complex Scheme***

Complex financial-based scheme includes:

- Rebates
- Stock supplied at zero cost (free stock)
- Dose/spend/volume capping
- Others

b) Performance-based Scheme

Performance or outcome-based scheme is a scheme where the rebate or supply of stock is based on **patient's response to treatment** or clinically tied to the endpoints measured in the future. It is also related to the patients' quality of life. It is considered at most times as complex scheme.

All refunds, rebates or free supply relating to PASc shall be made in accordance with the procedures set out in the PASc Approval Letter and it should be given to the MOH facilities which purchase the medicines.

3.0 PASc Proposal Submission

3.1 Eligibility Criteria

All medicines intended to be offered with PASc in MOH facilities must be **registered** with the Drug Control Authority (DCA) in Malaysia for **at least 12 months** at the time of submitting the proposal.

Medicines from a single source manufacturer or still under patent protection and biosimilars which are likely to have high budget impact can be considered for PASc. These medicines are categorised as follows:

a) New medicines with uncertain cost-effectiveness in real health care setting
b) Existing medicines in the MOHMF, which involves large volume of use and have extended indication or population.

3.2 Pre-submission Meeting

Pharmaceutical companies may have a pre-submission consultation with the secretariat at PPDD, prior to the submission of the PASc proposal for general advice and guidance on the operational feasibility of the proposed scheme. To request a pre-submission meeting, applicants are required to complete the PASc Pre-Submission Meeting Form (***Appendix 2***) and the form should be submitted to pascsecretariat@moh.gov.my.

The applicants are limited to **one** meeting per pending proposal submission and the request form should be sent at least **seven days** prior to the suggested meeting date.

No pre-submission consultation is allowed once the evaluation has started.

3.3 Submission Process

The general process for proposal submission for PASc implementation in MOH is outlined in ***Appendix 3***. All PASc proposals should be submitted to the †secretariat from the **Formulary Management Branch** at PPDD.

The proposed medicine for PASc must fulfil the eligibility criteria at the time of proposal submission. Pharmaceutical companies who wish to submit a PASc proposal should complete the appropriate PASc application form. All applications must be accompanied by a submission checklist as below:

a) Simple Scheme (financial-based)

- PASc Application Form (Simple Scheme) - ***Appendix 4***
- Checklist of Information (Simple Scheme) - ***Appendix 5***

b) Complex Scheme (financial- or performance-based)

- PASc Application Form (Complex Scheme) - ***Appendix 6***
- Checklist of Information (Complex Scheme) - ***Appendix 7***

These forms are available on the website (www.pharmacy.gov.my).

A brief explanation should be given for any missing information or document. Amendments to the proposal are not allowed after submission.

The secretariat has the right to reject any application that is incomplete or does not meet the eligibility criteria. Incomplete applications shall be returned to the applicant.

If pharmaceutical companies intend to submit PASc proposal for existing medicines in the central contract, the application forms should be submitted **one** year before the tender expires. For medicines listed in the central contract, pharmaceutical companies are only allowed to propose simple financial-based scheme (e.g. fixed percentage discount or a fixed price agreement).

†MOHMF Secretariat is responsible for the receipt of all PASc proposals.

4.0 Evaluation of PASc Proposal

4.1 Evaluation Process

All proposals are assessed in the context of the agreed key principles (***Appendix 1***), ensuring that the scheme is as simple as possible and financially acceptable; robust ethically, legally and operationally practical now and within the lifespan of the PASc. Information of the proposed scheme is strictly **CONFIDENTIAL** and is only for the intended recipient.

Pharmaceutical companies need to show that the proposed scheme is feasible, practical and can be monitored. If necessary further clarification will be sought whereby the applicant has a maximum of **seven** days to respond.

For medicines with multiple indications, one scheme should be applied across all the indications. However, applicant is permitted to submit a different PASc for a specific indication with justifications.

The monitoring mechanism for a complex scheme (financial- or performance-based) should be indicated in the application form.

Assessment of individual PASc proposals will be performed based on the type of schemes and associated complexity. The report on the feasibility of PASc implementation in MOH will be prepared based on the documentation submitted by the pharmaceutical company and where necessary, feedbacks from clinical and other experts.

No changes to PASc proposal are allowed during the evaluation process.

4.2 Pricing Arrangement

Pharmaceutical companies are also required to declare the price for medicines proposed for PASc by completing the PASc Medicine Price Declaration Form as per format in ***Appendix 8***. Pharmaceutical companies may be invited to attend a meeting with the PPDD for discussion on price arrangement or negotiation.

4.3 PASc Evaluation Timeframe & Approval

Evaluation timeframe is highly dependent on the type or complexity of the scheme and the categories of submission (parallel or non-parallel with dossier submission). Nevertheless, all PASc proposals will be processed **within 120 working days**.

The evaluation report prepared by the PPDD will be presented to PASc Panel and the PASc Panel Meeting will be scheduled within this timeframe. Meeting will be scheduled as required to ensure decisions are timely.

The Panel will consider and discuss on whether the PASc offered is acceptable for implementation and the decisions will be made based on consensus. Where appropriate, an opportunity will be provided to the pharmaceutical company at this stage to amend the scheme as to make it doable for implementation.

Meetings of the PASc Panel will not be held in public and all information to be discussed is considered as '**commercial in confidence'**. The PASc Panel has the right to reject the PASc proposed by the pharmaceutical company after considering recommendations in the evaluation report.

PASc Panel will make recommendations on the feasibility of the PASc to the MOH Controlling Officer whom will subsequently consider approval for a PASc.

4.4 Implementation Process and Communication

The PASc will be implemented in MOH facilities once approved by the MOH Controlling Officer. However, for PASc proposals submitted with a dossier, the PASc implementation of the proposed medicine will only take effect if the medicine is accepted for listing into the MOHMF. If a medicine is not accepted for listing, the PASc will not come into effect.

Final report will be prepared based on feedback from the PASc Panel and approval from the MOH Controlling Officer. Applicants and all MOH facilities will be informed of the final decision by the secretariat.

The effective date of the PASc, as approved by the MOH Controlling Officer will be indicated in the PASc Approval Letter.

5.0 Resubmission of PASc Proposal

The decision made by the MOH Controlling Officer is final and any disputes should be followed with a resubmission. If PASc proposal is not recommended or withdrawn by the pharmaceutical companies, any resubmission shall be treated as a new application.

The PASc resubmission process will follow the process of dossier resubmission for listing into MOHMF. The applicant can resubmit the same proposal for consideration after **three** months from the date of rejection, provided reason(s) for rejection have been addressed by the applicant. If the resubmission is also rejected, the second and the third resubmission can only be done at least **six months** and **twelve months**, respectively, from the date of rejection.

6.0 Renewal of PASc Proposal

A new PASc application form should be submitted to the PASc Secretariat for renewal for at least **six** months before the validity of the current PASc expires. For medicines listed in the central contract, the renewal of PASc application form should be sent **one** year before the tender expires.

For renewal of the complex scheme, PPDD will evaluate the effectiveness of the current scheme based on the findings from the current complex schemes (financial- or performance-based scheme).

MOH facilities are responsible for monitoring the patients initiated with the medicines listed under PASc according to the monitoring mechanism initially proposed during application. The monitoring parameters can be in the form of drug utilisation, rebates payment, monitoring of free stocks, patient's outcome or other relevant parameters.

The report on findings from the current complex scheme will be sent by MOH facilities to the PPDD annually or upon renewal of the scheme. This information is important as it will assist the PPDD in providing recommendations to the PASc Panel and the MOH Controlling Officer for renewal decision making.

Appendix 1

Key Principles for Patient Access Schemes (PASc) Implementation

1. PASc is an arrangement (agreement) between pharmaceutical company and MOH (payer/provider) in order to facilitate access to medicines that are likely to have high budget impact. It may come in a variety of mechanisms to address uncertainties about the performance of technologies or to manage the adoption of technologies in order to maximise their effective use, or limit their budget impact.

2. Through this agreement between the MOH and pharmaceutical companies, patients should benefit from any such scheme through improved access to new treatments on an equitable basis across all MOH facilities.

3. Schemes must be transparent, clinically robust, plausible (credible), practical and have 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. The full costs to MOH of any such agreement should be included in the costs submitted for consideration.

4. The proposed scheme must be negotiated and approved by an appointed committee in MOH.

5. PASc must be in compliance with MOH legislative requirements including formal agreements between MOH and a pharmaceutical company with regards to respective responsibilities including the burden of costs and protection of 'commercial-in-confidence' information. Any cumulative administrative burden of such schemes should remain manageable to all MOH staff in PPDD and facilities and the scheme should be consistent with the existing budget distribution in MOH.

6. Data obtained through implementation of a PASc remains the property of MOH which MOH retains the right to publish, subject to confidentiality outlined. Patient information must be protected and no patient-identifiable data should be shared as part of these schemes.

7. The validity of the scheme must be for a stated time period, under specific conditions and will be re-evaluated after the term end. Exit strategies for both parties must be clear. Continuity of care for patients must be addressed for both after scheduled completion of a scheme or should a scheme end prematurely. Any amendments to an accepted scheme must be submitted to the PASc Secretariat for consideration.

8. The implementation of PASc in MOH Malaysia will be reviewed on an ongoing basis.

Appendix 2

Pharmacy Practice & Development Division, Ministry of Health

PATIENT ACCESS SCHEME (PASc) PRE-SUBMISSION MEETING FORM

Type of Scheme (Please tick)

- ☐ **Financial-based Scheme**
  - ☐ **Simple Scheme**
  - ☐ **Complex Scheme**
- ☐ **Performance-based Scheme**

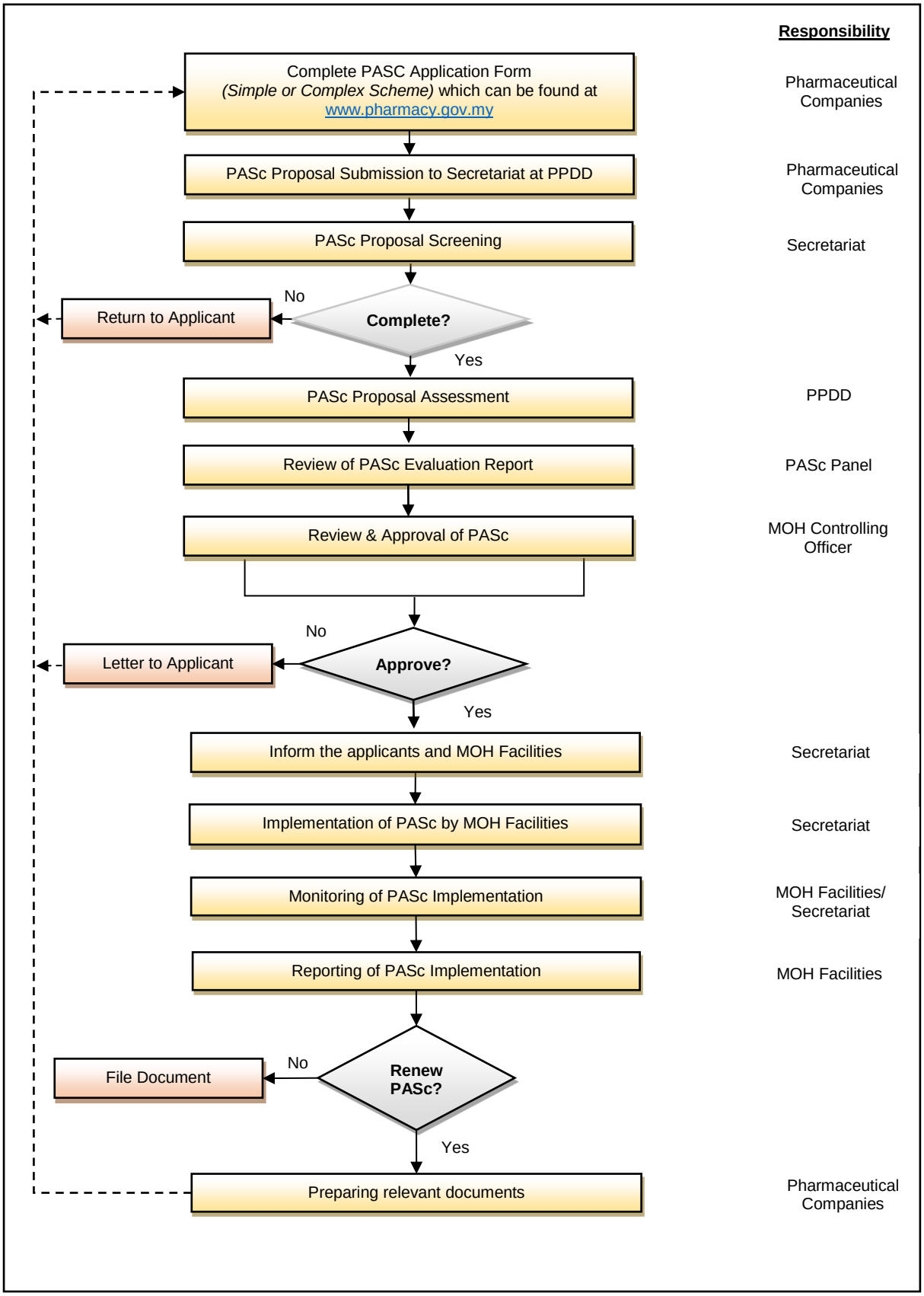
Section 1: PASc Background Information	
BACKGROUND INFORMATION	**DETAILS**
Applicant (Company Name)	*Insert company name*
Medicine name	*Insert the non-proprietary name and brand name*
Route of administration	*Insert the route of administration (e.g. oral, intravenous, subcutaneous, inhalation)*
Dosage form and strength(s)	*Provide dosage forms and strengths of the drug*
Approved Indication(s)	*Indication(s) approved by the Drug Control Authority, Malaysia*
Details of PASc	*Describe in brief PASc proposed*

Section 2: Details of Pre-submission Meeting Requested	
Date	*Insert the proposed date of meeting*
Time	*Insert the proposed time of meeting*
Name of officers attending the Meeting (Company)	*Name the officers who are going to attend the meeting (maximum three)*
Questions to be asked/ Matters to be discussed	*Write in brief the questions/ matters to be discussed*

Section 3: Contact Details	
Name of contact person (Company)	
Designation	
Contact no. **Email address**	
Date	

Appendix 3

Overview of MOH Patient Access Scheme (PASc) Process



Appendix 4

Pharmacy Practice & Development Division, Ministry of Health

For Office Use [PASc Registration Number ……./year]

PATIENT ACCESS SCHEME (PASc) APPLICATION FORM
Simple Scheme (Financial-based Scheme)

Note: Complete this application form for proposed simple schemes that comply with the standard PASc submission and criteria for simple scheme.

(Refer to Guideline on Proposal Submission for Patient Access Scheme (PASc) Implementation in Ministry of Health, Malaysia for further information and guidance on completion).

Criteria for Simple Scheme

- Offer a medicine price that is **LOWER** than the current price which applies to all supplies and preparations of the medicine and is valid for all current and future indication(s) and in all settings (within the duration of the PASc)
- Offer a **REDUCTION** of medicine price through percentage of discount applied to all purchases of medicines.
- Require **NO** additional administrative burden in purchasing of the medicine (*compared to situation without PASc*)
- Price remains in the MOH health system until the next review (e.g. MOHMF revision, contract revision or request from pharmaceutical company)

If the simple scheme criteria above cannot be fulfilled, applicant can consider to submit a complex scheme (Financial-/ Performance-based Scheme)

I) GENERAL INFORMATION

(Please tick)	☐ **New Application** ☐ **Renewal Application**
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(s)* ▪ *State the proposed indication(s) (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)*	

II) DETAILS OF PROPOSED PASc

Dosage Form, Strength(s)/ concentration(s)	Pack Size	Current Price (RM)	PASc Proposal	PASc Price (RM)
e.g. Tablet Paracetamol 500mg	e.g. *100 x 10 tablets*		*% discount or fixed price*	*Final price/ possible lower price*
Please confirm that the proposed scheme will apply to all current and future indications, for all preparations and in all settings. If **NO**, kindly describe the **reason(s)**. *(A simple PASc proposal should apply to all current and future indication(s). However, some schemes may be specific to a single indication and in this situation, usually a complex financial-based scheme or performance-based scheme may be considered)*		*Answer YES or NO.* *If NO, kindly state the reason(s)*		
Please describe briefly how the proposed discount will appear on the purchasing documents? *(if proposing for discount)*		*e.g. the discount will be shown on the original invoice to the purchasing institutions*		
Does the scheme requires any additional forms, registration or other administrative process to claim discount? If YES, kindly describe		*Answer YES or NO. If YES, kindly describe*		
Please indicate if the applicant would like the discount or price offered as part of the scheme to be considered **CONFIDENTIAL** by the MOH. Please describe the rationale.		*e.g. concern on the publication of prices and the impact on international price referencing*		
Please describe any possible impact that the scheme may give on the choice of treatment available in MOH		*e.g. price cheaper than other alternative available. Thus, it will resulted in treatment shift.*		
Kindly provide details of the duration of the proposed scheme and the justification.		*e.g. 3 years. Kindly state justification*		
There may be specific circumstances in which the applicant might change or withdraw the proposed PASc. Kindly describe these circumstances.		*e.g. revision of price worldwide*		
Please confirm the notice period that will be provided to PPDD due to withdrawal/ termination of the scheme.		*e.g. 3 months, 6 months*		

III) 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?

IV) ADDITIONAL INFORMATION

i. Please provide the estimated number of patients who will be treated with the medicine over the stated duration (including new future indications, if any).

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 the listing of new medicine in the MOHMF can be used

ii. Please state any other information that MOH should take into consideration when reviewing the scheme? If so, kindly provide the details.

V) COMPANY CONTACT DETAILS		
CONTACT DETAILS	**Name**	
	Designation	
	Address	
	Contact number	
	Email address	

Appendix 5

Pharmacy Practice & Development Division, Ministry of Health

CHECKLIST OF INFORMATION INCLUDED IN PASc APPLICATION FORM (SIMPLE SCHEME)

COMPANY NAME:	
(Please tick)	☐ **New application** ☐ **Renewal application**

NO.	PARTICULARS	TICK (✓)	*Please provide reasons if the particulars are not submitted/ filled*
I)	**GENERAL INFORMATION**		
1.	Generic name: *(Dosage form(s) & strength(s)/ concentration(s))*		
2.	Proprietary name		
3.	MAL registration no.		
4.	i) DCA indication ii) Proposed indication (new medicine for listing) iii) MOHMF indication (existing medicine in MOHMF) iv) Future indication to which PASc may apply		
5.	Category of medicine proposed for PASc		
6.	Suggested PASc start date		
7.	Duration of PASc		
8.	Existing PASc in Malaysia *(If any)*		
9.	Existing PASc in other countries *(If any)*		
10.	Patent expiry date *(medicines under patent protection)*		
II)	**DETAILS OF PROPOSED PASC**		
11.	i. Dosage form, strength(s)/concentration(s) ii. Pack size iii. Current price iv. PASc proposal (% discount/fixed price) v. PASc price		
12.	Proposed scheme will apply to all current and future indication(s), for all preparations, in all settings. (YES/NO).		*If NO, state the REASON*
13.	Description on how the proposed discount (if proposing for discount) will appear on the purchasing document.		
14.	Additional forms, registration or other administrative process to claim discount (YES/NO).		*If NO, describe*
15.	The discount or price offered as part of the scheme to be considered **CONFIDENTIAL** by MOH (YES/NO).		*State the rationale.*
16.	Possible impact that the scheme may give on the choice of treatment available in MOH		
17.	Duration of the proposed scheme & justification.		
18.	Description on specific circumstances in which the applicant might change/ withdraw the proposed PASc.		
19.	Notice period to PPDD due to withdrawal/ termination of the scheme.		

NO.	PARTICULARS	TICK (✓)	*Please provide reasons if the particulars are not submitted/ filled*
III)	**BENEFITS OF THE SCHEME**		
20.	Description on unmet need in the MOH & financial benefits that will be received by the MOH		
IV)	**ADDITIONAL INFORMATION**		
21.	Estimated no. of patients		
22.	Other information (if any)		
V)	**COMPANY CONTACT DETAILS**		
23.	**Contact Details** *(Name, designation, address, contact no., email address)*		

Appendix 6

Pharmacy Practice & Development Division, Ministry of Health

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 Guideline 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)*	

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 require 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*

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 :

i. ***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).*

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

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

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

- *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.*

IV) POPULATION

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

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

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?)*

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?

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

VIII) COMPANY CONTACT DETAILS

CONTACT DETAILS	**Name**	
	Designation	
	Address	
	Contact number	
	Email address	

Appendix 7

Pharmacy Practice & Development Division, Ministry of Health

CHECKLIST OF INFORMATION INCLUDED IN PASc APPLICATION FORM (COMPLEX SCHEME)

COMPANY NAME:	
(Please tick)	☐ **New application** ☐ **Renewal application**
Type of Complex Scheme	☐ **Financial-based** ☐ **Performance-based**

NO.	PARTICULARS	TICK (✓)	*Please provide reasons if the particulars are not submitted/ filled*
I)	**GENERAL INFORMATION**		
1.	Generic name: *(Dosage form(s) & strength(s)/ concentration(s))*		
2.	Proprietary name		
3.	MAL registration no.		
4.	i) DCA indication ii) Proposed indication (new medicine for listing) iii) MOHMF indication (existing medicine in MOHMF) iv) Future indication to which PASc may apply		
5.	Category of medicine proposed for PASc		
6.	Suggested PASc start date		
7.	Duration of PASc		
8.	Existing PASc in Malaysia *(If any)*		
9.	Existing PASc in other countries *(If any)*		
10.	Patent expiry date *(medicines under patent protection)*		
II)	**OPERATION OF THE SCHEME**		
11.	Rationale for choosing complex scheme		
12.	Indication(s) for the proposed medicine		
13.	Details of the scheme: i) Details of scheme operation (*setting, ordering, supply route, delivery and financial flow*). Flow diagram ii) Target group iii) Additional resources compared to without scheme iv) Possible impact that the scheme may give on the choice of treatment available in MOH v) Duration of the proposed scheme & justification. vi) Description on specific circumstances in which the applicant might change/ withdraw the proposed PASc. vii) Notice period to PPDD due to withdrawal/ termination of the scheme.		
III)	**COST BURDEN TO MOH**		
14.	Set up, implementation and operation cost		
15.	Additional treatment-related costs		
16.	Calculation of benefits		
17.	Mechanisms to minimise possibility of not requesting/claiming rebates of free stocks		

NO.	PARTICULARS	TICK (✓)	*Please provide reasons if the particulars are not submitted/ filled*
IV)	**POPULATION**		
18.	Estimated no. of patients		
V)	**MONITORING OF THE SCHEME & DATA COLLECTION**		
19.	Monitoring role & responsibilities (*applicant, institution & patient*)		
20.	Scheme monitoring method (*plan for monitoring*)		
21.	Data collection (*how will the data be collated & analysed, who is responsible for making sure data are readily available*)		
VI)	**BENEFITS OF THE SCHEME**		
24.	Description on unmet need in the MOH & financial benefits that will be received by the MOH		
VII)	**ADDITIONAL INFORMATION**		
25.	Additional information that important for reviewing the proposed scheme		
VIII)	**COMPANY CONTACT DETAILS**		
	Contact Details *(Name, designation, address, contact no., email address)*		

Appendix 8

ANP/PASC/004/2018v1

Pharmacy Practice & Development Division, Ministry of Health

PASc MEDICINE PRICE DECLARATION FORM

MEDICINE PRICING DETAILS			For Secretariat Use
1.	Type of PASc scheme	*Financial - / performance-based scheme*	
2.	Generic Name [specify dosage form(s) & strength(s)/ concentration (s)]	*Specify dosage form(s) & strength(s)/ concentration(s)*	
3.	Proprietary name	*Brand name of the product*	
4.	Product registration holder	*Company's name*	
5.	Manufacturer & country of origin	*Manufacturer's name*	
6.	Packaging size	*e.g. bottle of 5ml*	
7.	Price per packaging (RM) (Inclusive of 0.4% *e-Perolehan* Fee)		
8.	Price Per Unit (RM) (Inclusive of 0.4% *e-Perolehan* Fee)		
9.	Public Wholesale Price per unit **(RM)** in TWO ASEAN countries		
10.	Public Wholesale Price per unit **(RM)** in TWO **peer /* similar economic status* Countries from Other Region		
11.	Public Wholesale price per unit **(RM)** in Country of Origin		
12.	Patent validity date		

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.
2. Notification on the medicine price listed in MOH Medicines Formulary will be issued by Medicine Price Management Branch, Pharmacy Practice & Development Division, Ministry of Health Malaysia.

7.0 References

1. Adamski, J., Godman, B., Ofierska-Sujkowska, G., Osinska, B., Herholz, H., Wendykowska, K. et al. 2010. *BMC Health Services Research*, 10(153), 3-16.
2. Klemp, M. & Fronsdal, K. B. 2011. What principles should govern the use of managed entry aggreements? *International Journal of Technology Assessment in Health Care*, 27(1), 77-83.
3. Lu, C.Y., Lupton, C., Rakowsky, S., Babar, Z.D., Ross-Degnan, D. & Wagner, A.K. 2015. Patient access schemes in Asia Pacific markets: Current experience and future potential. *Journal of Pharmaceutical Policy and Practice*, 8(6), 1-12.
4. Marsden, G., Towse, A. & Henshall, C. 2016. Assessing value, budget impact and affordability to inform discussions on access & reimbursements: Principles and practice with special reference to high cost technologies. (HTAi Asia Policy Forum Meeting)
5. NHS Scotland. 2017. Patient access scheme (PAS) guidance V4.0.
6. Patient Access Schemes Liaison Unit at NICE. 2009. Process for advising on the feasibility of implementing a patient access scheme. PASLU Process Guide V1.3.
7. Pauwels, K., Huys, I., Vogler, S., Casteels, M. & Simoens, S. 2017. Managed entry aggreements for oncology drugs: Lesson from the European experience to inform the future. *Frontiers in Pharmacology*, 8(171), 1-8.
8. Williamson, S. & Thomson, D. 2010. A report into the uptake of patient access scheme in the NHS. *Clinical Pharmacist*, 2:1 – 4.

8.0 Guideline For Applicant

- Application Form can be obtained from Pharmaceutical Services Programme official website: **www.pharmacy.gov.my.**

- All PASc application forms should to be sent to:

  Director
  Pharmacy Practice and Development Division
  Ministry of Health Malaysia
  Lot 36, Jalan Universiti
  46200 Petaling Jaya
  Selangor.
  (u/p: MOH Medicines Formulary Secretariat)

- Any inquiries or concerns regarding PASc application process can be forwarded to PASc Secretariat via email: **pascsecretariat@moh.gov.my**

Pharmacy Practice & Development Division
Ministry of Health Malaysia
Lot 36, Jalan Universiti,
46200 Petaling Jaya,
Selangor, Malaysia.

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Website : www.pharmacy.gov.my