MH 36:9\004

[dd Month yyyy]

Dear [name],

**Call for Proposal for Subsidy Listing**

and/or claims and benefits under the MediShield Life (MSHL) Scheme

The Government of the Republic of Singapore (the “**Authority**”), represented by the Agency for Care Effectiveness of the Ministry of Health, seeks proposals (“**Proposals**”) for the evaluation of [title of evaluation] for the[title of evaluation] (“**Relevant Indication**”) for inclusion on the list of drugs eligible for subsidy under the Standard Drug List or Medication Assistance Fund and/or claims and benefits under the MediShield Life (MSHL) Scheme.

1. Proposals are to be submitted in FORM A to the MOH Drug Advisory Committee (DAC) Secretariat [MOH\_DAC\_Secretariat@moh.gov.sg], no later than **1200 hours** sharp on the closing date communicated to you by the Agency for Care Effectiveness in relation to the Relevant Indication.
2. The Authority shall be under no obligation to accept the lowest or any Proposal.
3. The Authority shall have the right to seek clarifications from respondents, and may call for revised Proposals from all respondents following such clarifications. Any fresh Proposal submitted by a respondent shall supersede all previous Proposal(s) submitted by that respondent.

Yours sincerely,

Ms Lin Liang

Head (HTA)

Agency for Care Effectiveness

*for Permanent Secretary (Policy and Development)*

MINISTRY OF HEALTH

**Proposal for Subsidy Listing**

**and/or Claims and Benefits under the MediShield Life (MSHL) Scheme**

Agency for Care Effectiveness,

Ministry of Health

# FORM A: DRUG PRICING PROPOSAL

To: The Government of the Republic of Singapore (the “**Authority**”), represented by the Agency for Care Effectiveness of the Ministry of Health

Section 1: Technical Specifications and Costs

We, [name of company in block letters] (the “**Respondent**”), hereby offer and undertake, on the acceptance of this Proposal, to offer the following drug(s) with the following specifications for sale to Public Healthcare Institutions (as defined in section 2) at the following cost price(s), in accordance with the Terms and Conditions in Section 2:

***Table A1: Drug Prices***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item No.** | **Drug, strength and pharmaceutical form** | **Indication(s)@** | **Cost price per unit, excluding GST (SGD)#** | **Percentage reduction from usual cost price in public sector (%)** |
| 1. | [name of drug, strength and pharmaceutical form] |  | / [specify units] |  |
| @ Final subsidy/claim criteria will be based on MOH Drug Advisory Committee’s recommendations.  #Each cost price of a drug in this column applies irrespective of the eligibility of the patient to receive any claim or benefit under the MediShield Scheme or any subsidy for that drug. For the avoidance of doubt, each cost price of a drug in this column applies even where that drug is dispensed or to be dispensed to a patient who is not eligible to receive claim or benefit under the MediShield Scheme or any subsidy for that drug. | | | | |
| PAP or other arrangements proposed: Yes/No (details in Appendix) | | | | | |
| Companion diagnostic test(s) to be included as part of proposal: Yes/No (Please provide details under section 7 of the Appendix) | | | | | |

2 We shall ensure that the cost price per unit charged by the Respondent to a Public Healthcare Institution for a Drug (as defined in Section 2) that is dispensed or to be dispensed to any patient of that Public Healthcare Institution shall not exceed the cost price per unit set out in Table A1 above corresponding to that Drug for as long as that Drug is listed on a Drug List (as defined in Section 2), irrespective of that patient’s eligibility to receive any claim or benefit under the MediShield Scheme or any subsidy for that Drug. For the avoidance of doubt, this paragraph 2 applies to a unit of a Drug even if that unit is dispensed or to be dispensed for a patient who is not eligible to receive any claim or benefit under the MediShield Scheme or any subsidy for that Drug.

3 To assist the Authority in assessing this Proposal, we have duly completed and hereby submit the tables and other information in the Appendix for the Authority’s consideration. We confirm and warrant that the information set out in the Appendix is complete, up-to-date, accurate and not misleading. For as long as this Proposal remains valid (as defined in paragraph 4 below), we undertake and agree to inform the Authority of any change or update to the tables and other information set out in the submitted Appendix, within seven (7) days from the time that we first become aware of such change or update. In the event that the Authority seeks clarification on this Proposal, we shall provide full and comprehensive responses within seven (7) days of notification from the Authority.

4 This Proposal is valid for eighteen (18) calendar months from [deadline for submission of the Proposal].

5 We warrant, represent and declare that we are duly authorised to submit and sign this Proposal, receive any instruction, give any information, accept any contract and act for and on behalf of [name of company in block letters].

Dated this [date] day of [month], [year]

|  |  |
| --- | --- |
| Respondent’s Company or Business Registration No:  Respondent’s postal address:  Respondent’s electronic mail address: | Respondent’s official Stamp: |

Signed for and on behalf of the Respondent by its authorised signatory:

|  |
| --- |
| Signature:  Name:  Designation: |

Section 2: Terms and Conditions

1. **ACCEPTANCE OF PROPOSAL**
   1. The issue by the Authority of a letter of acceptance accepting this Proposal (the “**Letter of Acceptance**”) shall create a contract (“**Contract**”) binding the Respondent to offer for sale to all Public Healthcare Institutions each of the drugs specified in the Letter of Acceptance (each, a “**Drug**” and collectively, the “**Drugs**”) at a cost price per unit not exceeding the cost price per unit of that Drug (excluding goods and services tax) set out in this Proposal, on and from the date specified in the Letter of Acceptance as the Price Effective Date corresponding to that Drug, for as long as that Drug is listed on any Drug List and subject to any further terms and conditions contained in the Letter of Acceptance. Where the Respondent has one or more existing agreements of sale of a Drug with any of the Public Healthcare Institutions as at the Price Effective Date applicable to that Drug, the Respondent undertakes to take all reasonable steps to vary each of such agreements so that on and after the Price Effective Date applicable to that Drug, the cost price per unit of that Drug offered to each of the Public Healthcare Institutions does not exceed the cost price per unit of that Drug (excluding goods and services tax) set out in this Proposal.
   2. These Terms and Conditions shall apply to the Contract.
   3. For the purpose of this Proposal, and any Contract formed upon the Authority’s acceptance of this Proposal:
      1. “**Adviser**” means:
         1. ALPS Pte. Ltd. (company registration number: 201805065E); or
         2. any of the Authority’s agents, contractors (including subcontractors), consultants or advisers (including legal advisers) engaged in, or in relation to, the performance or management of the Contract;
      2. “**Drug List**” means the list of drugs eligible for subsidy under the Standard Drug List or Medication Assistance Fund or any other subsidy scheme, or eligible for claims and benefits under the MediShield Life (MSHL) Scheme;
      3. “**Parties**” means the Authority and the Respondent, and “**Party**” means any of them;

* + 1. “**Permitted** **Disclosure**” means
       1. disclosure of (1) the prices at which the Respondent will sell the Drugs to all or any of the Public Healthcare Institutions and/or (2) any amount paid by the Respondent to the Authority under any risk sharing deed relating to any Drug (or any formula relating thereto), by the Authority:

1. to all Public Healthcare Institutions;
2. to the Authority’s Advisers or employees (including any employee of any related body corporate) solely in order to comply with obligations, or to exercise rights, under the Contract;
3. to the Authority’s internal management personnel, solely to enable effective management or auditing of Contract-related activities;
4. to the responsible Minister;
5. in response to a request by the Parliament of Singapore;
6. to a court, tribunal or other legally constituted enquiry or for the purposes of any alternative dispute resolution process;
7. within the Authority, or to and within another Singapore government agency or statutory board, where this serves Singapore’s legitimate interests;
8. where required by law to be disclosed;
9. for the administration of any Drug List, including the negotiation or administration of any existing or future risk sharing deed or the addition of new drugs onto any Drug List; and/or
10. to the extent such information is in the public domain otherwise than due to a breach of clause 1.6 below;
    * + 1. disclosure of market data, invoices and/or utilisation data relating to any Drug by the Authority to any person (including any company which is in the same or similar business as the Company), for the negotiation or administration of any existing or future risk sharing deed, including determining the amounts due under any existing or future risk sharing deed;
      1. “**Public Healthcare Institutions**” means:
         1. the public healthcare institutions and polyclinics set out in Table A2; and
         2. each other public healthcare institution or polyclinic in Singapore as the Authority may notify the Respondent from time to time;
      2. “**Singapore Dollars**”, “**S$**” or “**SGD**” means the lawful currency of the Republic of Singapore; and
      3. references to a person include any company, limited liability partnership, partnership, business trust, unincorporated association or government agency (whether or not having separate legal personality).
    1. For as long as a Drug is listed on a Drug List, the Respondent shall inform the Authority of any failure or inability to supply that Drug to any Public Healthcare Institution, within seven (7) days of the Respondent’s failure to supply that Drug or of the Respondent becoming aware of its inability to supply that Drug, where:
11. a failure to supply would have occurred when the Respondent fails to deliver the amount of that Drug requested by any Public Healthcare Institution within the period requested by that Public Healthcare Institution; and
12. an inability to supply means the Respondent is unable to deliver any amount of that Drug requested by any Public Healthcare Institution within the period requested by that Public Healthcare Institution;
    1. In consideration of the above, the Authority shall be bound by the obligations of the Authority under the Contract.
    2. Save for a Permitted Disclosure, the Authority shall not otherwise make publicly available the prices at which the Respondent will sell the Drugs to all or any of the Public Healthcare Institutions.
    3. The Respondent shall continue to comply with the Confidentiality Agreement entered into between the Respondent and the Authority, relating to, among others, the Authority’s consideration of drugs for inclusion on one or more lists of drugs eligible for subsidy, as may be amended or supplemented from time to time.
    4. Without prejudice to clause 1.7 above, except with the prior consent in writing of the Authority, the Respondent shall not disclose any information relating to the content of this Proposal or the Contract, or any part thereof, to any third party.

* 1. Clauses 1.6 to 1.8 above shall survive the termination or expiry of the Contract.

1. **PRICE REVIEW AND DETERMINATION OF LISTING**
   1. From time to time (whether before, on or after the creation of the Contract), including, without limitation, upon the occurrence of any of the following events or circumstances:
2. the entry or anticipated entry into the Singapore market of:
   * + 1. a new me-too compound of the same drug class or a new non-inferior drug as that of any Drug;
       2. a new biosimilar or generic version to any Drug; or
       3. a new medicine that is indicated for use in combination with any Drug;
3. upon an expansion to the list of registered indications for any Drug;
4. upon the availability of evidence, to the Authority or otherwise, that suggests there are or there will be changes to the cost-effectiveness of any Drug;

## there is no legally binding written agreement in effect between the Respondent and any Public Healthcare Institution for the supply of any Drug by the Respondent to that Public Healthcare Institution;

## the Respondent fails to deliver the amount of any Drug requested by any Public Healthcare Institution within the period requested by that Public Healthcare Institution; and

## the Respondent is unable to deliver any amount of any Drug requested by any Public Healthcare Institution within the period requested by that Public Healthcare Institution,

the Authority shall have the right to do one or more of the following in its absolute discretion, and the Respondent shall have no claim for any damages or compensation:

1. call for a re-evaluation of, and re-evaluate, the drugs listed on the Drug Lists (or any of them);
2. review prices of one or more of the drugs listed on the Drug Lists (or any of them);
3. include or remove any drug (including, without limitation, any one or more of the Drugs) from any one or more of the Drug Lists, and/or amend any one or more of the Drug Lists in any way; and
4. notwithstanding Clause 6.1 below, unilaterally amend, supplement and/or add to the conditions or other provisions set out in the Letter of Acceptance by providing not less than 30 days’ written notice of the revision to the Respondent.
   1. The Authority may terminate the Contract and recover from the Respondent the amount of any loss resulting from such termination, if the Respondent shall have offered or given or agreed to give to any person any gift or consideration of any kind as an inducement or reward for doing or forbearing to do or for having done or forborne to do any action in relation to the obtaining or execution of the Contract with the Authority or for showing or forbearing to show favour to any person in relation to any contract with the Authority, or if the like acts shall have been done by any person employed by the Respondent or acting on its behalf (whether with or without the knowledge of the Respondent) or if in relation to the Contract, the Respondent or any person employed by it or acting on its behalf shall have committed any offence under Chapter 9 of the Penal Code 1871 or the Prevention of Corruption Act 1960 or shall have abetted or attempted to commit such an offence or shall have given any fee or reward the receipt of which is an offence under Chapter 9 of the Penal Code 1871 or the Prevention of Corruption Act 1960.
5. **SUSPENSION AND TERMINATION OF THE CONTRACT**
   1. The Authority shall, after giving seven (7) days prior written notice to the Respondent, have the right to suspend or terminate the Contract if the Authority is affected by any state of war, acts of God or other circumstances seriously disrupting public safety, peace or good order of the Republic of Singapore.
   2. If the Respondent defaults in its performance of the Contract, the Authority may issue a notice of default to the Respondent informing the Respondent of its default. The Respondent shall, within thirty (30) days of the date of the notice of default, remedy the default. If the Respondent fails to remedy the default, the Authority shall have the right to immediately remove the Drugs (or any one or more of them) from one or more of the Drug Lists, and/or terminate the Contract by way of a written notice to the Respondent, in each case, without the Authority being liable therefor in damages or compensation.
   3. If on or after the Price Effective Date applicable to a Drug but before the Contract is terminated or expires, the Respondent sells that Drug to any of the Public Healthcare Institutions (the “**Relevant PHI**”) at a cost price per unit (each, a “**Defaulting Price**”) exceeding the cost price per unit of that Drug set out in this Proposal (each, a “**Proposal Price**”), the Authority shall have the right (in addition to and without prejudice to all other rights or remedies available, including the Authority’s right to terminate the Contract pursuant to clause 3.2) to require the Respondent to pay as liquidated damages for each unit of that Drug sold to the Relevant PHI a sum calculated in accordance with the following formula:

Liquidated sum per unit of that Drug = (Subsidies disbursed)Default – (Subsidies disbursed)Proposal

Where:

(Subsidies disbursed)Default = the average amount of subsidies disbursed by the Authority to the Relevant PHI per unit of that Drug based on that Defaulting Price; and

(Subsidies disbursed)Proposal = the average amount of subsidies which would have been disbursed by the Authority to the Relevant PHI per unit of that Drug based on that Proposal Price.

* 1. In the event that a Drug is to be removed from a Drug List as a result of any of the events set out in Clauses 2.1(d), 2.1(e), 2.1(f) or as a result of a default in the Respondent’s performance of the Contract, the Respondent shall draft and publish not later than one month before such removal takes effect, in a daily English newspaper circulating generally in Singapore a public statement, vetted by the Authority, explaining the reasons why that Drug is to be removed from a Drug List.
  2. The Authority shall have the right, at its sole discretion, to elect to claim general damages in common law from the Respondent instead of imposing liquidated damages under clause 3.3.
  3. Clauses 3.3 to 3.5 shall survive the termination or expiry of the Contract.

# TRANSFER AND ASSIGNMENT

* 1. The Respondent shall not assign any of its rights or transfer any of its rights or obligations under the Contract except with the prior written consent of the Authority (such consent not to be unreasonably withheld).
  2. If the Respondent:

1. is subject to a merger, takeover, re-organisation or any other arrangement which results in it ceasing to supply a Drug in Singapore; or
2. sells or otherwise disposes of its interest in a Drug to another person,

it must:

1. notify the Authority of that event prior to its occurrence; and
2. provide the Authority with enough detail of the event to allow the Authority to determine the action it requires.
   1. On a notice being given pursuant to clause 4.2, the Authority may, in its absolute discretion, notify the Respondent that the Respondent is to, and the Respondent must:
3. procure the novation of the Contract to the relevant successor on terms acceptable to the Authority; or
4. procure the relevant successor to enter into a new contract with the Authority on terms acceptable to the Authority.
5. **REMEDIES**
   1. The right and remedies of the Parties under the Contract are cumulative and are in addition and without prejudice to any rights or remedies a Party may have at law or in equity. Further, no exercise by a Party of any one right or remedy under the Contract shall operate so as to hinder or prevent the exercise by it of any other right or remedy under the Contract, or any other right existing at law or in equity.
6. **VARIATION**
   1. Save as expressly provided in the Contract (including, without limitation, this Proposal, these Terms and Conditions and the Letter of Acceptance), no variation whether oral or otherwise in the terms of this Proposal or the Contract shall apply thereto unless such variation shall have first been expressly accepted in writing by the authorised signatories of both Parties.
7. **WAIVER**
   1. In no event shall any delay, failure or omission on the part of either of the Parties in enforcing or exercising any right, power, privilege, claim or remedy, which is conferred by the Contract, at law or in equity, or which arises from any breach by either Party, be deemed to be or be construed as, (a) a waiver thereof, or of any other such right, power, privilege, claim or remedy, in respect of the particular circumstances in question, or (b) operate so as to bar the enforcement or exercise thereof, or of any other such right, power, privilege, claim or remedy, in any other instance at any time or times thereafter.
   2. No waiver by the Authority of any breach of the Contract shall be deemed to be a waiver of any other or of any subsequent breach.
   3. Any waiver granted by the Authority under the Contract must be in writing and may be given subject to conditions. Such waiver under the Contract shall be effective only in the instance and for the purpose for which it is given.
8. **ENTIRE AND WHOLE AGREEMENT**
   1. The Contract contains the entire and whole agreement between the Parties relating to the subject matter of the Contract and supersedes all prior written or oral commitments, representations, arrangements, understandings or agreements between the Parties. Each Party warrants to the other Party that it has not entered into the Contract on the basis of any prior written or oral commitments, representations, arrangements, understandings or agreements between them.
9. **GOVERNING LAW**
   1. This Proposal and the Contract shall be governed by and construed in accordance with the laws of the Republic of Singapore.
10. **SEVERABILITY**
    1. In the event any provision in the Contract is determined to be illegal, invalid or unenforceable, in whole or in part, such provision or part of it shall, to the extent it is illegal, invalid or unenforceable, be deemed not to form part of the Contract and the legality, validity and enforceability of the remainder of the Contract shall not be affected.
11. **RIGHTS OF THIRD PARTIES**
    1. A person who is not a party to the Contract shall have no right under the Contracts (Rights of Third Parties) Act 2001 to enforce any term of the Contract.

1. **DISPUTE RESOLUTION**
   1. In the event of any dispute, claim, question or disagreement arising out of or relating to the Contract or its subject matter or formation (a “**Dispute**”), no Party shall proceed with mediation or any form of dispute resolution unless the Parties have complied with the procedure in this Clause 12.1:
2. the Parties shall negotiate in good faith with a view to resolution of such Dispute;
3. if a Dispute is not settled within thirty (30) days of negotiation, or such longer period as the Parties may agree in writing, the Parties shall refer the Dispute to a senior executive or senior officer of each Party respectively (each, a “**Senior Executive**”) and shall furnish to the Senior Executives the full particulars of the Dispute. Each Senior Executive shall promptly meet with his or her counterparts and shall use his or her best endeavours to settle the Dispute through consultation and negotiation in good faith and in a spirit of mutual cooperation. Any settlement of the Dispute by agreement between the Senior Executives shall be final and binding on the Parties; and
4. if the Dispute is not settled by agreement between the Senior Executives within 30 days after the date of referral of the Dispute to the Senior Executives, or such longer period as the Parties may agree in writing, any Party may proceed to give the other Party a written request for mediation as contemplated in Clauses 12.2 to 12.4.
   1. In the event of any Dispute and if no agreement is reached under Clause 12.1 above, no Party shall proceed to any form of dispute resolution unless the Parties have made reasonable efforts to settle the Dispute through mediation in accordance with the mediation procedure of the Singapore Mediation Centre. The Parties shall be deemed to have made reasonable efforts in accordance with this Clause 12.2 if they have gone through at least one mediation session at the Singapore Mediation Centre.
   2. A Party who receives a written notice for mediation from the other Party shall consent and participate in the mediation process.
   3. The mediation session is to commence no later than ninety (90) days from the date of the written notice of mediation failing which either Party may proceed to arbitration.
   4. Failure to comply with Clause 12.2 or 12.3 shall be deemed to be a breach of the Contract.
   5. In the event of any Dispute and if no agreement is reached under Clause 12.1 or 12.2 above, the Dispute shall be referred to and finally resolved by arbitration in Singapore in the English language by a sole arbitrator in accordance with the Arbitration Rules of the Singapore International Arbitration Centre (“**SIAC**”) for the time being in force which rules are deemed to be incorporated by reference into this Clause. The seat of the arbitration shall be Singapore. The arbitrator shall be agreed upon between the Parties, or on failure to agree within thirty (30) days of a written proposal by one Party to the other Party, to be appointed by the SIAC acting in accordance with the SIAC Rules. This arbitration agreement shall be governed by and construed in accordance with the laws of the Republic of Singapore.
   6. This clause 12 shall survive the termination or expiry of the Contract.
5. **CORRESPONDENCE**
   1. Subject to Clause 13.2, any notice, request, waiver, consent or approval (“**Notice**”) shall be in writing and shall be deemed to have been duly given or made when it is delivered by hand or by prepaid registered post or fax to the Party as follows:
6. in the case of the Respondent, the Respondent’s postal address set out in Section 1 above; and
7. in the case of the Authority, the following address:

The Ministry of Health

Agency for Care Effectiveness (ACE)

College of Medicine Building

16 College Road, Singapore 169854.

* 1. Any Notice may be made by the Authority to the Respondent by electronic mail or other electronic means and shall be deemed to have been duly given or made when it is sent to the Respondent’s electronic mail address set out in Section 1 above.
  2. Either Party may change its address and (in the case of the Respondent) electronic mail address referred to above by giving the other Party written notice of the change.

1. **SURVIVING PROVISIONS**
   1. Any provision of the Contract that expressly or by implication is intended to come into or continue in force on or after termination or expiry of the Contract, including Clauses 1.6 to 1.8, 2 (Price Review and Determination Of Listing), 3.3, 3.4, 3.5 3.6, 5 (Remedies) to 13 (Correspondence) and this Clause 14, shall survive the termination or expiry of the Contract.

**Table A2. List of Public Healthcare Institutions**

|  |  |
| --- | --- |
| 1 | Alexandra Hospital |
| 2 | Ang Mo Kio – Thye Hua Kwan Hospital |
| 3 | Changi General Hospital |
| 4 | Institute of Mental Health/Woodbridge Hospital |
| 5 | Jurong Community Hospital |
| 6 | Khoo Teck Puat Hospital |
| 7 | KK Women’s and Children’s Hospital |
| 8 | National Cancer Centre Singapore |
| 9 | National Centre for Infectious Diseases |
| 10 | National Dental Centre Singapore |
| 11 | National Heart Centre Singapore |
| 12 | National Healthcare Group Pharmacy |
| 13 | National Healthcare Group Polyclinics |
| 14 | National Neuroscience Institute |
| 15 | National Skin Centre |
| 16 | National University Cancer Institute |
| 17 | National University Centre for Oral Health |
| 18 | National University Heart Centre |
| 19 | National University Hospital |
| 20 | National University Polyclinics |
| 21 | Ng Teng Fong General Hospital |
| 22 | Outram Community Hospital |
| 23 | Ren Ci Community Hospital |
| 24 | St. Andrew’s Community Hospital |
| 25 | Singapore General Hospital |
| 26 | Sengkang General Hospital |
| 27 | Sengkang Community Hospital |
| 28 | St Luke’s Hospital |
| 29 | Singapore National Eye Centre |
| 30 | SingHealth Polyclinics |
| 31 | Tan Tock Seng Hospital |
| 32 | Tan Tock Seng Hospital Integrated Care Hub |
| 33 | Woodlands Health |
| 34 | Yishun Community Hospital |

# Appendix

1. ***Volume and current cost price@,#***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Number of units sold in the last 12 months in public sector**  **[ month/ year to month/ year]** | **Usual cost price per unit in public sector excluding GST (SGD)** | **Number of units sold in the last 12 months in private sector**  **[ month/ year to month/ year]** | **Usual cost price per unit in private sector excluding GST (SGD)** |
| [name of drug, strength and pharmaceutical form] | [specify units] |  | [specify units] |  |

@In the event that a drug is yet to be sold in Public Healthcare Institutions, please indicate the cost price at which the Respondent is planning to sell that drug, in the absence of any subsidy.

#For as long as this Proposal remains valid, the Respondent shall inform the Authority of any change to the cost price of the drug.

1. ***Patient Assistance Programmes (PAPs) currently in place (if any)^***

|  |  |
| --- | --- |
|  | **Please provide details**  **(eligibility criteria, level of subsidy, differences among Public Healthcare Institutions and patient numbers)** |
| [name of drug, strength and pharmaceutical form] |  |
| [name of drug, strength and pharmaceutical form] |  |

***^***For as long as this Proposal remains valid, the Respondent shall inform the Authority of any update to any PAP.

1. ***Ongoing plans/proposals for Patient Assistance Programmes (PAPs) (if any)^***

|  |  |
| --- | --- |
|  | **Please provide details**  **(expected eligibility criteria, proposed level of subsidy, Public Healthcare Institutions involved, expected differences among Public Healthcare Institutions, and expected patient numbers)** |
| [name of drug, strength and pharmaceutical form] |  |
| [name of drug, strength and pharmaceutical form] |  |

***^***For as long as this Proposal remains valid, the Respondent shall inform the Authority of any update to any PAP.

1. ***Existing agreements to sell the Drugs to Public Healthcare Institutions listed in Table A2 (if applicable)\****

|  |  |  |
| --- | --- | --- |
|  | **Contracting Party** | **Date of expiry of agreement** |
| [name of drug, strength and pharmaceutical form] |  |  |
| [name of drug, strength and pharmaceutical form] |  |  |

\*For as long as this Proposal remains valid, the Respondent shall inform the Authority of any update to any of the existing agreements.

1. ***Proposal for Patient Assistance Programme (PAP) or Risk sharing arrangements***

If the Respondent is desirous of proposing a PAP or risk sharing arrangements for MOH’s consideration to list the drug or drugs on one or more lists for subsidy and/or claims or benefits under MSHL, please include details of the proposed arrangement within this section of this Appendix:

**Patient Assistance Programmes**

Please describe:

1. Details of the proposed arrangement;
2. The annual cost of the drug, should the arrangement be accepted and implemented; and
3. Information on the PHIs the Respondent have engaged, with adequate demonstration of the PHI(s) acceptance of and commitment towards working with the Respondent in implementing the proposed arrangement. For avoidance of doubt, proof of agreement (i.e. signed documents by the Head of Department and pharmacy manager) is required as part of the proposal.
4. Justification for proposing this PAP instead of a more direct mechanism to improve affordability (e.g. direct price reductions), and confirm that all other options for the DAC’s consideration to list the Drug or Drugs on the Drug List have been explored, and that acceptance of this proposed arrangement is but a last resort.
5. Any proposed PAP must minimally apply to all Singapore Citizens and Permanent Residents with no further eligibility criteria.

|  |
| --- |
|  |

**Price-Volume Agreement (PVA)**

Please indicate the proposed Expenditure Caps for the Drugs and the corresponding reimbursement rate if the total annual expenditure for the Drugs exceeds the expenditure cap for that year:

|  |  |  |
| --- | --- | --- |
| **Year** | **Expenditure Caps**  **(excluding GST, SGD)** | **Reimbursement Rate** |
| 1, 20XX | S$[Insert Expenditure Cap] | [insert reimbursement rate between 0% to 100%]. |
| 2, 20XX | S$[Insert Expenditure Cap] |
| 3, 20XX | S$[Insert Expenditure Cap] |
| 4, 20XX | S$[Insert Expenditure Cap] |
| 5, 20XX | S$[Insert Expenditure Cap] |

* + - * 1. Under the Price-Volume Agreement (“**PVA**”), the Respondent agrees to pay the Authority (i.e. the Singapore Government, as represented by MOH) a reimbursement amount, if the Total Public Healthcare Expenditure on the PVA drug(s) for any Year exceeds the Expenditure Cap for that Year.
        2. The reimbursement amount is calculated in accordance with the following formula:
        3. “**Total Public Healthcare Expenditure**” means an amount in Singapore Dollars, calculated in accordance with the following formula:

Total Public Healthcare Expenditure = Sum of Public Healthcare Expenditure for all PVA Drugs

Where:

Public Healthcare Expenditure for each PVA Drug = an amount in Singapore Dollars that is derived in accordance with the following steps:

1. first, determine the total number of units of that PVA Drug Choose an item. in that Year (the “**Total Quantity**”);
2. second, for each unit of that PVA Drug that is part of the Total Quantity, identify the price (excluding GST) paid by the relevant Public Healthcare Institution to the Company (including any agent, contractor or subcontractor of the Company) to procure that unit of that PVA Drug (each, an “**Actual Price**”);
3. third, for each Actual Price, calculate an amount (each, a “**Relevant Amount**”) in accordance with the following formula:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Relevant Amount of an Actual Price | = | the number of units of that PVA Drug that is part of the Total Quantity and supplied to the Public Healthcare Institutions at that Actual Price | × | that Actual Price |

1. fourth, add all Relevant Amounts of all the Actual Prices. The sum of all such Relevant Amounts shall be referred to as the “**Total** **Sum**”; and
2. lastly, the Public Healthcare Expenditure for that PVA Drug is the amount in Singapore Dollars equal to:
   * 1. the Total Sum,

less

* + 1. any amount paid to or due to be paid to the Authority or to any other person designated by the Authority, under a Special Pricing Arrangement in relation to that PVA Drug Choose an item. in that Year. “Special Pricing Arrangement” means, in relation to a drug, any agreement that entitles the Authority to recover an amount for each unit or number of units of the drug sold to one or more of the Public Healthcare Institutions.
       - 1. “**PVA Drugs**” refer to drugs that are subject to the PVA.
         2. “**PHI Patient**” means any patient of a Public Healthcare Institution.
         3. “**MS**” means a fraction which is calculated by applying the following formula:

*Note: Where the Drugs are the only PVA Drugs, MS will equal to 1.*

Please justify the expenditure caps and reimbursement rate proposed. It should include derivation of any patient numbers, along with data sources and assumptions applied (e.g. incidence/prevalence rates, treatment duration and estimated uptake rates).

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***6. Existing arrangements or programmes for companion diagnostic test(s) for the Drug or Drugs indicated in Table A1 (if any)***

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|  | **Companion diagnostic test details**   * *Name* * *Commercial or lab-developed test* * *Manufacturer (if commercial test)* * *Biomarker(s) tested* * *Type of test (e.g. single variant, single gene, gene panel, WES)* * *Molecular technique of test (e.g. IHC, NGS)* * *Test scope of genetic tests (e.g. structural variant, copy number variant)* * *Sensitivity and specificity (with supporting documents)* * *Turnaround time of test* | **Patient eligibility criteria, including any applicable test restriction (e.g. number of tests per lifetime)** | **Designated partner lab performing the tests**   * *Name of lab (and accreditations)* * *Local or overseas provider* | **Cost per test (in SGD)**   * *Total cost of test* * *Cost borne by patient* * *Cost borne by drug company* | **Patient number per year** |
| [name of drug, strength and pharmaceutical form] |  |  |  |  |  |
| [name of drug, strength and pharmaceutical form] |  |  |  |  |  |
| [name of drug, strength and pharmaceutical form] |  |  |  |  |  |

1. ***Proposed arrangements or programmes for companion diagnostic test(s) for the Drug or Drugs indicated in Table A1 (if any)***

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