

Australian Terms & Conditions

BMS MEDICINE ACCESS - STANDARD TERMS AND CONDITIONS

1. BACKGROUND & SCOPE

A definitions section is included at the end of these Terms and Conditions ("Terms").

Bristol-Myers Squibb Australia Pty Ltd (ABN 33 004 333 3220) "BMS" is a pharmaceutical company that develops, manufactures and makes available innovative pharmaceutical products, including Free Issue Products, to licensed Healthcare Providers for specific Patients on a compassionate and goodwill basis.

These Terms apply and are binding on BMS and Healthcare Provider ("Parties") where BMS at its discretion agrees to provide Free Issue Products to a Healthcare Provider for a Patient's use as part of BMS Medicine Access or where BMS otherwise expressly incorporates these Terms.

2. CONDITIONS OF ISSUE

Any Free Issue Products BMS agrees to provide are as described in the applicable Product Information.

Without limiting any other terms or conditions, the Healthcare Provider must ensure or must procure that Free Issue Products delivered to the Healthcare Provider are stored in conditions compatible with the Free Issue Products' eventual usage, in accordance with any applicable requirements in the relevant Product Information or as notified by BMS from time to time, including refrigeration and security requirements and in a manner which enables easy and rapid recall by strength, batch code, product description or patient program.

Healthcare Provider grants to BMS (and its permitted agents and representatives) full rights of access and egress to any premises where Free Issue Products are stored, or where records in respect of Free Issue Products are retained (including pharmacy stock rooms), by the Healthcare Provider for such purposes as BMS may reasonably require, including to carry out any inspection of quality and storage conditions of the Free Issue Products, where recovery of Free Issue Products is required under these Terms, or for any other reason as may be reasonably requested by BMS.

Any costs associated with providing the Free Issue Product after it is delivered are to be borne by the Healthcare Provider, including for example, administration, storage, staff training and dispensing costs.

BMS reserves the right in its sole discretion to stop providing at any time (subject to reasonable notice) BMS Medicine Access and the Free Issue Products without any present or future liability or other legal obligation to a Healthcare Provider, Patient or any other party at any time.

3. OBLIGATIONS OF THE HEALTHCARE PROVIDER

The Healthcare Provider will (and will procure that its agents, representatives and contractors):

- comply with all applicable laws and regulations, including all applicable privacy laws, good clinical practices and ethical standards, anti-bribery and corruption laws affecting the administration and use of the Free Issue Products under BMS Medicine Access;
- ensure Free Issue Products are administered to Patients in compliance with the relevant Product Information; obtain and maintain all approvals and authorisations required under applicable laws to obtain, supply and administer the Free Issue Products to Patients under and pursuant to these Terms;
- ensure that each Patient meets all eligibility requirements as notified to the Healthcare Provider by BMS from time to time prior to enrolling a Patient into BMS Medicine Access;
- enrol Patients in the BMS Medicine Access only in accordance with the process for enrolment determined by BMS, which will include using an online portal ("Portal") unless BMS advises otherwise; and
- without limiting the foregoing paragraphs, prior to administering the Free Issue Products:
- obtain, or procure the necessary and informed consent and relevant authorisations from Patients in written form as may be approved, or required to be evidenced and/or issued to Patients by BMS; and
- properly and fully disclose to all Patients the potential risks and benefits, including as may be set out in the Product Information and/or any supporting materials and documentation provided by BMS to accompany the Free Issue Products.

The Healthcare Provider will promptly report to BMS all Adverse Events and Other Reportable Events (both defined at <http://www.globalbmsmedinfo.com/>) associated with a BMS product; such report shall not be provided any later than one business day or three calendar days, whichever is earlier after becoming aware of the event. The Healthcare Provider will report the information to the BMS contact for receipt for Australia and if that contact is unavailable shall use the contact for the United States. The Healthcare Provider will comply with applicable laws, including privacy laws, in relation to such reports and will comply with BMS' reasonable follow-up requests.

4. PATIENT ENROLMENT

The Healthcare Provider must enrol eligible Patients (via the Portal) once all necessary consents and pre-enrolment conditions have been met as set out in these Terms and/or as specified by BMS from time to time. The Healthcare Provider must provide accurate, complete and up-to-date information during the online registration and enrolment process and otherwise as specifically required by BMS. Such information may include for example, a Patient's initials, weight, date of birth and treatment history/summary.

5. ORDERS

The Healthcare Provider will use the Portal to place an order for Free Issue Products ("Order") under BMS Medicine Access, giving BMS reasonable advanced notice, taking into account the nature of the Free Issue Product and any directions given by BMS in respect to placing Orders. The Healthcare Provider must only place Orders when needed by a Patient and the Free Issue Products must not be stockpiled.

Whilst BMS will use reasonable endeavours to supply the Free Issue Products, no Order will be binding on BMS unless the Order is accepted in writing or the Free Issue Product is dispatched.

If BMS Medicine Access is closed, Orders will no longer be able to be placed.

6. DELIVERY AND ACCEPTANCE

Unless otherwise agreed, BMS will meet the cost of packing, freight and transportation charges. Any shipping dates are approximate and are not guaranteed. If no dates are specified, delivery shall be within a reasonable timeframe.

The Free Issue Products will be deemed delivered by BMS to the Healthcare Provider when delivered to the premises, site or warehouse of the Healthcare Provider or other nominated site. If the delivery address has been incorrectly stated by the Healthcare Provider, any associated costs or liabilities will be borne by the Healthcare Provider.

The Healthcare Provider will inspect the Free Issue Products within a reasonable time after delivery to the Healthcare Provider, and will notify BMS and the carrier in writing if it is apparent that there is a shortage of the Free Issue Products (as against the Order), the Free Issue Products are defective or damaged (for example, as a result of any temperature excursions) or if the packs or shipping cartons in which the Free Issue Products are packed have been damaged on delivery, or if the Free Issue Products are beyond the shelf life stated on packaging.

The Healthcare Provider must retain damaged or defective Free Issue Products in the state, condition and location in which they were delivered for inspection and/or collection by BMS, its nominee and/or the carrier, or at the discretion and cost of BMS, return the Free Issue Products to BMS (at its notified address) or destroy the Free Issue Products, each in accordance with BMS' instructions from time to time.

The Healthcare Provider shall be deemed to have accepted the Free Issue Products after the Healthcare Provider has had seventy-two (72) hours to inspect the Free Issue Products after delivery to the Healthcare Provider and has not notified BMS of any defects or damages.

The sole extent of BMS' liability in respect of any defects, damage or fault in the Free Issue Products when delivered will be limited to replacing the Free Issue Products and reissuing to the Healthcare Provider, subject always to the extent that the relevant defect, damage or fault arose during or prior to delivery of the Free Issue Products.

7. RISK AND TITLE

The Free Issue Products shall be at the risk of BMS until delivery to the Healthcare Provider. Title to, risk in and ownership of the Free Issue Products will pass to the Healthcare Provider immediately on delivery.

8. QUALITY AND PACKING

Free Issue Products supplied by BMS are formulated, packaged, labelled and accompanied by the necessary instructions for use, including the Product Information and Consumer Medicine Information, in order to comply with appropriate regulatory and legal requirements in Australia.

9. RETURNS

The Healthcare Provider will (and will procure that its agents and contractors) comply with all reasonable instructions of BMS in relation to any product hold, product recall requirement or any

cancellation of the Free Issue Products, BMS Medicine Access or any other corrective action reasonably taken by or on behalf of BMS in respect of the Free Issue Products or BMS Medicine Access at any time before or after delivery to the Healthcare Provider.

10. CONFIDENTIALITY

The Parties acknowledge the importance of Confidential Information and that the Confidential Information of each other is (respectively) valuable to it and its business. Each party must keep the Confidential Information of the other secret and confidential and may only use it for the purposes of performing its obligations under these Terms.

11. DATA AND PRIVACY

Notwithstanding any other provision of these Terms, the Healthcare Provider must ensure at all times that, in the collection, use, storage and other handling of Personal Information (including Patient Personal Information) and where relevant BMS Personal Information:

- it complies with all applicable privacy laws, and BMS' privacy and data protection policies, procedures and protocols where specifically notified by BMS to the Healthcare Provider from time to time;
- the consents obtained from Patients in accordance with these Terms are sufficient to cover the collection, use, storage and other handling of Personal Information as contemplated by these Terms, including the transfer and disclosure of Personal Information to BMS and to other Healthcare Providers or Prior Treatment Providers;
- without limiting the foregoing, it has and will maintain all necessary consents to provide to BMS aggregated, anonymised and/or deidentified information relating to a Patient's use and disposal (if applicable) of the Free Issue Products;
- that all Patient Data and content is up to date, complete and accurate at all times when using the Free Issue Products under the BMS Medicine Access; and
- it establishes and maintains appropriate privacy, security and information risk measures and protocols to safeguard against the unauthorised access to, misuse, loss, corruption or alteration of any Personal Information in respect of the Free Issue Products, including any information relating to Patient access and use of the Free Issue Products.

The Healthcare Provider acknowledges that Patient Personal Information will be collected, used, handled, disclosed, stored and deleted by BMS in accordance with the functions and activities authorised by the Healthcare Provider and Patients and as otherwise required in order to provide the Free Issue Products in the manner contemplated by these Terms, and in accordance with the BMS Privacy Policy.

BMS confirms that it handles all Personal Information in accordance with all applicable privacy laws and the BMS Privacy Policy.

Without limiting the foregoing, BMS may also generate sets of deidentified, anonymised and aggregated data from the Patient Data that is provided by a Healthcare Provider ("De-identified Data"). Any De-identified Data is and will be fully anonymised and de-identified in accordance with all applicable laws and does not and will not contain any Personal Information at any time.

The Healthcare Provider acknowledges, and will ensure all patients whose Personal Information the Healthcare Provider provides to BMS acknowledges, that BMS may use De-identified Data for marketing, research and other commercial purposes including aggregating the De-identified Data information across all Patients for the purpose of regulatory and reimbursement submissions, improving BMS services, and improving patient treatment.

If the Healthcare Provider becomes aware of any improper use of BMS Data or Patient Data, including any actual or suspected security incident, any potential or actual data breach, or any issue of any kind that may potentially jeopardise Patient Data or BMS Data in any way, the Healthcare Provider must and will ensure its agents and contractors must, at the earliest possible convenience, notify BMS setting out in full the known details, and (where the suspected incident or breach has arisen as a result of any act or omission of the Healthcare Provider) the scope of remedial measures proposed or being undertaken to resolve the suspected or actual incident or breach. The Healthcare Provider will keep BMS updated of all known details relating to the incident or breach and if requested allow BMS to participate in the Healthcare Provider's assessment and remediation of the incident or breach.

12. PUBLICATION

The Healthcare Provider must not publish, market, disseminate or otherwise disclose any information relating to a Patient's use or handling of the Free Issue Products (including the terms of access), whether in scientific literature or otherwise, without the prior written consent of BMS. Where BMS provides consent to the publication in accordance with the above, then the Healthcare Provider must:

- only seek to publish the methods, results of, and conclusions from, the data, subject to this Clause and in accordance with any applicable laws;
- ensure that BMS receives a draft copy of any proposed publication at least 30 (thirty) Business Days before it is submitted to any third party (including a publisher or reviewer);
- upon any request by BMS, delay publication of any proposed manuscript or presentation for a period of up to 90 (ninety) days to allow BMS to take any measures necessary to protect its Confidential Information or proprietary or intellectual property rights; and
- address any comments from BMS relating to the removal of BMS' Confidential Information or the accuracy of the Free Issue Products' data or conclusions about the Free Issue Products' data.

If the Healthcare Provider has not received any comments from BMS on the proposed publication within 30 (thirty) Business Days of giving notice to BMS, the Healthcare Provider may:

- proceed to publication;
- acknowledge in all publications BMS' support of any studies in a manner that may be reasonably notified to the Healthcare Provider by BMS from time to time.

Where information is published in accordance with this Clause, BMS may use, copy and disseminate any manuscript prepared by the Healthcare Provider following its publication.

13. COMPLIANCE

The Healthcare Provider, on receiving reasonable notice, will provide BMS and/or its agents with all reasonable assistance, documentation and evidence to show compliance with these Terms. BMS agrees that it will take all reasonable steps to avoid unreasonable interruption to the Healthcare Provider's business when exercising BMS' rights under this clause.

14. INSURANCE

The Healthcare Provider shall maintain insurance coverage sufficient to cover the provision of Free Issue Products to Patients.

15. NO WARRANTIES

To the extent permitted by law, access to and use of Free Issue Products by a Healthcare Provider, or any other party are provided wholly on 'as is' basis, without any warranty or condition of any kind and whether express or implied and including any guarantees under the Australian Consumer Law ("ACL") provided that nothing in this clause is intended to limit any rights a patient may have as a consumer under the ACL.

BMS also CANNOT guarantee that the information or data which accompany the Free Issue Products or required when using the Free Issue Products is up-to-date or error free. Any minor updates to the Product Information or Consumer Medical Information of Free Issue Products by BMS will be submitted to and published by the TGA. You can find the most up to date Data Sheet for the Free Issue Products here: <https://www.tga.gov.au>.

In addition, BMS does NOT guarantee, pledge or promise that the Healthcare Provider or its Patients' use of Free Issue Products will meet any or all of the Patient's needs or requirements.

16. WARRANTIES OF THE HEALTHCARE PROVIDER

In performing its obligations under these Terms, the Healthcare Provider warrants on a continuing basis to BMS that:

- it will perform its obligations under these Terms in a manner that reflects favourably at all times, and will not harm or otherwise cause detriment to the good name, goodwill and reputation of BMS;
- it is not aware of any inappropriate inducement and that it will not take any action on BMS' behalf which would conflict with applicable antibribery or anti-corruption laws;
- it has all the necessary consents, rights and licences to grant to BMS the rights in and to use Patient Data (including Personal Information) as are contemplated under these Terms; and
- the use by BMS of Patient Data in the manner contemplated in these Terms will not infringe or is not likely to infringe, misappropriate or violate any party's intellectual property rights or rights of publicity or privacy.

17. LIABILITY

Nothing in these Terms will limit either party's liability in respect of any claim for liability which cannot be limited or excluded by law.

BMS will not be liable to the Healthcare Provider or any other party for any indirect losses, loss of profits or anticipated profits, loss of expected future business, damage to reputation or goodwill, nor

any claim for consequential compensation whatsoever (however caused), which arises in connection with the supply of the Free Issue Products or related services by BMS.

BMS will not be liable for the use of, or any onward supply by the Healthcare Provider of, Free Issue Products, including in respect of Free Issue Products whose expiration date has passed by the time of issue to a Patient (where the Free Issue Product was in date at the time of delivery) or for any Free Issue Products that have deteriorated as a result of an act or omission of the Healthcare Provider after the Free Issue Products were delivered by BMS or its nominee or carrier. The Healthcare Provider will fully indemnify and hold BMS harmless against any Losses resulting from a breach of this provision by the Healthcare Provider.

Nothing in these Terms excludes, restricts or modifies any guarantee, warranty, term or condition, right or remedy implied or imposed by applicable law which cannot lawfully be excluded, restricted or modified.

The use of any Free Issue Products outside the scope of the approved Product Information is not endorsed by BMS and BMS will have no liability to the Healthcare Provider or any Patient or third party under these Terms.

18. INDEMNITY

Without prejudice to BMS's other rights and remedies, the Healthcare Provider will indemnify and keep indemnified BMS, its group companies and their employees and agents on demand in full against any Losses incurred or suffered as a result of any claim brought by any third party in respect of Losses, injury or damage caused by any Free Issue Products which arises as a result of any negligent or reckless action or omission of the Healthcare Provider (or its agents or contractors).

19. TERMINATION

BMS may terminate its BMS Medicine Access arrangement with the Healthcare Provider if the Healthcare Provider materially breach these Terms or any other terms upon which the Healthcare Provider receives Free Issue Products.

BMS may also terminate this arrangement at any time on reasonable prior written notice to the Healthcare Provider.

If BMS closes any BMS Medicine Access, the Healthcare Provider will promptly return in good condition, undamaged, all remaining and unused stock of Free Issue Products. BMS will pay for the transportation costs of returning such stock but all other costs, including in respect to administrative costs, are to be borne by the Healthcare Provider.

20. FORCE MAJEURE

BMS will not be liable in any way for Losses arising directly or indirectly from the failure or delay in performing any obligation under these Terms caused by any circumstances outside its control, including vandalism, accident, break down or damage to machinery or equipment, fire, flood, earthquake, storm, governmental action, strike, epidemic, pandemic, lock-out or other industrial disputes (whether or not involving BMS' employees) or shortage of materials or fuel. On the occurrence of such event, BMS may, at its own election, perform, suspend performance of or terminate all or any Orders which have not been delivered.

21. DISPUTE RESOLUTION

A party claiming that a dispute has arisen must give written notice to the other party setting out the nature of the dispute.

The parties' must meet in Melbourne within 5 (five) Business Days of receipt of a dispute notice to seek to resolve the dispute by negotiation. A party may, by notice to the other, refer the dispute to mediation to be conducted by the Australian Disputes Centre under its then-current mediation rules and guidelines for resolution if the dispute remains unresolved more than 20 (twenty) Business Days after receipt of a dispute notice.

If a dispute is referred to mediation:

- any meetings organised will be held in Melbourne or such other place as may be agreed by the parties;
- the parties agree to pay costs as directed by the mediator; and
- each party may be represented by a duly qualified legal practitioner.

Either party may commence legal proceedings if the dispute has not been referred to mediation within 25 (twenty-five) Business Days of receipt of a dispute notice or has not been resolved through mediation.

22. NOTICES

Any notice, approval or consent required to be given under this agreement must be in writing (which includes email).

23. MISCELLANEOUS

These Terms:

- supersede all previous statements or any previous terms relating to the supply of Free Issue Products;
- excludes any terms provided by the Healthcare Provider; and
- must not be supplemented or varied without the written consent of BMS.

No waiver of a right or remedy under these Terms is effective unless it is in writing and signed by the party granting it.

These Terms (including any non-contractual disputes arising) are governed by the laws of Victoria, Australia and remain subject to the exclusive jurisdiction of the courts of Victoria, Australia.

The parties are independent contractors and nothing in these Terms constitutes a fiduciary relationship or an agency, partnership, trust, joint venture, or employment relationship between the parties. No party has authority to bind any other party.

The parties do not intend that these Terms be enforceable or for the benefit of any third party.

24. DEFINITIONS AND INTERPRETATION

In these Terms the following definitions apply:

"BMS" means Bristol-Myers Squibb Australia Pty Ltd (ABN 33 004 333 3220) of Level 2, 4 Nexus Court, Mulgrave, VIC 3170, Australia.

"BMS Data" has the meaning given to it in the definition of Confidential Information.

"BMS Medicine Access" means the 'Patient Support Programs' providing no cost or reduced cost access to BMS medicines, 'Exceptional Use' or compassionate supply and such other similar supply arrangements under which BMS may, in its discretion, supply Free Issue Products, as each may be specified by BMS from time to time.

"Confidential Information" means in relation to a party, information that is by its nature confidential, is designated by that party as confidential, or the other party knows or ought reasonably to know is confidential, and includes including any information relating to the financial affairs, assets or liability of a party, or any information relating to the internal management of a party, its personnel, policies, plans, strategies, customers, suppliers, products or services, and in the case of BMS, includes any BMS data provided or otherwise made available to or accessed by the Healthcare Provider in connection with the provision of the Free Issue Products under these Terms (BMS Data). Confidential Information does not include information or material which:

- is or becomes generally known to the public other than through a breach of these Terms;
- at the time it was first disclosed to a party, was already in that party's lawful possession;
- is developed independently by a party; or
- is disclosed to a party by a third party entitled to disclose it.

"Consumer Medicine Information" means the product documents written by BMS that provide information on the safe and effective use of the Free Issue Products.

"Data Sheets" means the product information documents approved by TGA in respect to a Free Issue Product.

"Free Issue Products" means any TGA approved medicine (and their accompanying documentation and materials supporting access and use) which are offered on a no cost or reduced cost basis, or as compassionate stock by BMS in its sole discretion under the BMS Medicine Access and/or as may be specified by BMS from time to time.

"Healthcare Provider" means a licenced healthcare professional or body, including but not limited to a physician, GP (general practitioner), pharmacist or other like licence holders.

"Losses" means all losses, liabilities, fines, penalties, damages, claims and interest, and all related costs and expenses (including any and all legal costs (on a full indemnity basis), and costs of investigation, litigation, settlement, judgment, appeal, interest and penalties) and including those which are prospective or contingent and those the amount of which for the time being is not ascertained or ascertainable.

"Order" has the meaning in clause 5.

"Patient" means an individual who is under the professional care of a Healthcare Provider and who is approved by a Healthcare Provider and BMS as eligible for access to the BMS Medicine Access.

"Patient Data" means any data, information, records, reports and/or other similar information on a Patient collected, created or generated pursuant to or prepared in connection with the Free Issue Products or any Patient use of the Free Issue Products, including the Personal Information of a Patient collected via the online registration and enrolment process, or otherwise provided or collected as a result of any Patient use of the Free Issue Products or otherwise collected by BMS in its dispensing of the Free Issue Products. Patient Data includes, without limitation, any aggregation, anonymisation and/or de-identification of Patient data, information, records and reports relating to the Free Issue Products.

"Personal Information" means personal information as defined by the Privacy Act and for the purposes of these Terms includes sensitive information and health information, as such related terms are defined in the Privacy Act.

"Portal" has the meaning given to it in clause 3.

"Prior Treatment Provider" means an organization, other than BMS, which has provided any TGA approved medicine to a Patient which meets the eligibility criteria for that Patient to be enrolled in BMS Medicines Access.

"Privacy Act" means the Australian Privacy Act 1988 (Cth) and the Australian Privacy Principles (APPs) and all guidelines, privacy codes, codes of conduct, directives or orders made under it, as each are amended and/or updated from time to time.

"Product Information" means the product information document approved by the TGA in respect to a Free Issue Product.

"Terms" means the Terms set out above, as amended, updated or repealed from time to time by BMS.