

# Consent Form

## Consent to participate in the J&J withMe Patient Support Program Consent to disclosure and use of personal information

**PATIENT CONSENT** to participate in free of charge Patient Support Program ("PSP" or "Programme") relating to  
..... ("Product") offered  
by JANSSEN PHARMACEUTICA (PTY) LTD (T/A  
JOHNSON & JOHNSON INNOVATIVE MEDICINE) ("J&J").

Patient name: .....

Doctor name: .....

1. I confirm that my Doctor discussed all viable treatment options with me and I subsequently elected to be treated with the Product under the supervision and guidance of my Doctor. My decision was not influenced by J&J and or the existence of the PSP.
2. I wish to, and accordingly consent to, participate in the PSP which includes the following services rendered by J&J ("Services"), as applicable:
  - a) Reimbursement assistance - liaise with my Doctor and medical scheme to assist with the reimbursement processes.
  - b) Injection scheduling and reminder service - coordinate the scheduling of my injections with my choice of pharmacy and nurse, as well as send me reminders for my subsequent injection dates.
  - c) Script and medicine approval expiration reminder service. Noting Doctor will re-assess condition and may or may not continue same treatment.
3. I understand that I will not be required to pay any form of consideration to the Doctor or J&J for participation in the PSP.
4. I understand that for J&J to provide me with the Services, J&J will require and have access to my personal and health information and will be required to share such information with others. Such personal information and health information will include my:
  - a) name, surname, ID number, contact numbers and e-mail address, physical and postal address;
  - b) sex, age, weight, employment status, race (if required for the medicine application documents that my treating Doctor completes for consideration of treatment and medical aid reimbursement);
  - c) medical aid scheme, option plan and medical aid number;
  - d) prescribed treatment, diagnosis, medical history, treatments, medical procedures and special investigations, blood and laboratory results;
  - e) treating physician and contact details; and
  - f) dates of follow-up appointments,collectively referred to as "**Personal and Health Information**".
5. As such, I consent to the privacy notice annexed as ANNEX 1, and in addition:
  - a) grant J&J permission to receive from, and share with, my Doctor, medical aid, chosen pharmacy, treatment centre and/or my legal guardian/parent/curator, to the extent applicable ("**Authorised Parties**"), the relevant Personal and Health Information and understand that Janssen may do so in any form, including e-mail, and Janssen cannot be held responsible for, and hereby indemnify J&J against any claim arising relating to, the safe keeping of my Personal and Health Information by such Authorised Parties;
  - b) understand that the following Personal and Health Information, required for the management of the Services, will be captured and securely kept within the BioAccess Patient Management system of J&J: prescribed J&J medication / diagnosis / Doctor and Doctor contact details / script related information / medicine approval related information / treatment dates (if applicable to my prescribed J&J medication);
  - c) understand that J&J will safely manage and store my Personal Information for the period necessary to fulfil the purposes outlined in this consent unless a longer retention period is required or allowed by law or to otherwise fulfil a legal obligation; and
  - d) understand that it is my responsibility to let J&J know of any changes to my Personal and Health Information.
6. Where medication is dispensed by a pharmacy, I agree to J&J:
  - a) providing Personal and Health Information, script and medicine approval to my pharmacy; and enquiring at my pharmacy as to whether medicine was claimed, ordered and received.
7. I understand that the PSP is there to provide support only. J&J and my Doctor cannot and does not make any guarantees or warranties in relation to any of the Services, or the impact of its products or the Services on my health. Janssen cannot be held liable for any co-payments or if an appeal / authorisation for treatment has not been successful. Janssen and its staff or contractors cannot provide any healthcare service or advice, and they will refer me back to my Doctor on all such matters. I will contact my Doctor if I have any questions on my treatment, or changes to my health status. I indemnify J&J against any claims or losses arising from any matter contemplated in this clause or otherwise in this consent and as a result of my participation in the PSP, save where such liability cannot be excluded in terms of applicable law, for example where J&J has acted grossly negligent or under willful misconduct.
8. I understand that J&J is required to report any side effects that I might experience during treatment to J&J Global Medical Safety. In such an event the safety event will be reported according to company requirements, however patient identifiable information is kept confidential.
9. I confirm that I:
  - a) am giving this consent freely and without any undue influence or any influence from my Doctor or J&J or any other party;
  - b) have read, discussed with my Doctor, and subsequently understand the content and implications of the J&J withMe PSP, this consent and the Privacy Notice set out below;
  - c) have the right to withdraw this consent at any time by contacting the J&J withMe team on 0800 11 21 01 or [jps@its.jnj.com](mailto:jps@its.jnj.com). Such withdrawal will not affect my rights to care or treatment, including access to J&J products (as well as the Product) and I am free to continue to see my Doctor and obtain healthcare from my Doctor and/or his/her practice; and
  - d) am fully and legally competent to sign the consent and understand that it is my responsibility to let J&J know of any changes to my legal status.

**Johnson & Johnson**

Initials: .....

Signed at: ..... on .....

|  |   |
|--|---|
| <p>.....</p> <p><b>Patient Signature</b></p> <p><b>Patient Contact Number:</b> .....</p> <p><b>Patient ID Number:</b> .....</p> <p><b>Patient email address:</b> .....</p> <p><b>Patient Medical Aid:</b> .....</p> <p><b>Patient Medical Aid Plan:</b> .....</p> <p><b>Patient Medical Aid No.:</b> .....</p> | <p>.....</p> <p><b>Signature of Guardian / parent / curator</b><br/>(where and as applicable) <b>OR if none</b>, Doctor and patient <u>may elect</u> to have a witness sign<br/>(if no guardian / parent / curator co-signing)</p> <p><b>Name:</b> .....</p> <p><b>Contact number</b><br/>(not required for witness):</p> <p>.....</p> <p><b>Email address</b><br/>(not required for witness):</p> <p>.....</p> |
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**By signing the above, the patient's guardian / parent / curator (where and as applicable) confirms:**

- I understand that my personal information provided in this consent as the representative of the patient is required for purposes of providing the Services and as such I consent to the privacy notice annexed as ANNEX 1 as if, and to the extent, it applies to my personal information;
- I understand that my personal information will be transferred via e-mail to the patient's medical aid, the patient's chosen pharmacy, treatment centre (if applicable) ("Authorised Parties") and I grant J&J permission to transfer my personal information to the Authorised Parties. I understand that J&J cannot be held responsible for, and hereby indemnify J&J against any claim arising relating to, the safe keeping of my personal information by such Authorised Parties;
- I understand that my personal information, required for the management of the Services, will be captured and securely kept within the BioAccess Patient Management system of J&J;
- I understand that J&J will safely manage and store my personal information for the period necessary to fulfil the purposes outlined in this consent unless a longer retention period is required or allowed by law or to otherwise fulfil a legal obligation; and understand that it is my responsibility to let Janssen know of any changes to my personal information.

..... Signed at: ..... on .....

**Doctor Signature**

**By signing the above, the Doctor confirms:**

- I am a registered mental health care practitioner and duly qualified to treat the Patient; and during the presence of the Patient at the time of Patient's signature of this consent, I confirmed, to the best of my knowledge / observation, and in my professional opinion, the Patient:
  - a. read and understands the extent of the consent and Privacy Notice set out below;
  - b. understands that he/she has the right to withdraw this consent at any time and that this withdrawal will not affect his/her rights to care or treatment, including access to J&J products (and the Product);
  - c. is fully competent to sign the consent;
  - d. was given the opportunity to ask any questions related to the PSP, this consent and the Privacy Notice; and
  - e. understands that this consent is given freely and voluntarily; and
- there are no apparent reasons to believe that the Patient is incapable (as a result of his/her vision, communication, physical health, mental health, hearing capabilities, intellectual capabilities, and or any other reason) to sign and give the consent to participate in the PSP and sign the Privacy Notice.

# Privacy Notice

Agreement of authorisation to collect, use and disclose personal health information: privacy notice

JANSSEN PHARMACEUTICA (PTY) LTD (T/A JOHNSON & JOHNSON INNOVATIVE MEDICINE) ("J&J") cares about your privacy and wants you to be familiar with how we collect, use and disclose personal information.

With your consent, we will use your personal information to manage our relationship with you, in accordance with our Privacy Notice, below. You may withdraw your consent at any time. Your personal information will be shared with our affiliates, service providers, and other third parties, as described in our Privacy Notice. Your personal information will be transferred to countries outside of your country of residence, including the United States, which may provide for different data protection rules than in your country.

- 1. Information collection:** With your consent, J&J will collect your personal information from you for the purposes of administering the Program, evaluating the effectiveness of the Program, and communicating information about the Program to you.
- 2. Disclosure of information:** We may disclose your personal information to our affiliates for the purposes described in this Privacy Notice. A list of our affiliates is available at <http://www.investor.jnj.com/sec.cfm> (click on the link to Form10K, Exhibit 21, under "SEC Filings"). We may also disclose the personal information to unaffiliated third parties, but only to service providers that we use to support our business.
- 3. Your Privacy Rights:** You have the right to request to review the personal information we have collected about you, as well as the right to request correction, deletion, blocking, data portability and restriction of our use of such information. You may also withdraw your consent to our processing of your personal information for the purposes described above at any time. You can make a request or withdraw your consent by contacting our J&J WithMe team at [jps@its.jnj.com](mailto:jps@its.jnj.com).
- 4. Cross-Border Transfer:** The use and disclosure of personal information contemplated in this Privacy Notice may involve a transfer of the information to jurisdictions located outside your country of residence, including the United States, which may provide for different data protection rules than in your country. Appropriate contractual and other measures are in place to protect your personal information when it is transferred.
- 5. Data Retention:** We will retain your personal information for as long as needed or permitted in the light of the purpose(s) for which it was obtained. The criteria used to determine our retention periods include: (i) the length of time we have an ongoing relationship with you and provide the service to you; (ii) whether there is a legal obligation to which we are subject; and (iii) whether retention is advisable in light of our legal position (such as in regard to applicable statutes of limitations, litigation, or regulatory investigations).
- 6. Lodging a Complaint:** You may lodge a complaint with the Information Regulator (South Africa). Contact information for the Information Regulator is: JD House, 27 Stiemens Street, Braamfontein, Johannesburg, 2001; Tel 010 023 5200; e-mail [enquiries@infoeregulator.org.za](mailto:enquiries@infoeregulator.org.za)

I understand that I may refuse to sign this Authorisation, and that I do not need to sign this Authorisation to receive services from my current and future healthcare providers and insurers; however, if I refuse to sign this Authorisation, I will not be able to participate in the Program.

I have read the above agreement, and, by signing this document, I give explicit consent to the use and disclosure of my Health Information pursuant to this Authorisation. I also authorise J&J to receive my Health Information from my current healthcare provider.