

Managed Access Programs / Post-Study Drug Supplies Patient Privacy Notice/Consent Template

Dear Patient,

Your treating physician is submitting a request to Novartis for your treatment or your child's/ward's treatment. This privacy notice describes how Novartis South Africa (Pty) Ltd, at Magwa View, Magwa Crescent West, Waterfall City, Jukskei View , Gauteng, 2090, South Africa (hereinafter referred to as "Novartis"), uses and otherwise processes your personal information as responsible party, in accordance with applicable data protection laws, including the Protection of Personal Information Act, 2013 (POPIA)..

In this privacy notice, references to "we" or "us" mean Novartis. "You" means the patient whose personal information is processed as described in this document. If you receive this document because your treating physician has submitted a request for access to treatment for your child or ward, the term 'you' refers to your child or ward for whom the request is being made.

What data do we collect and what happens with it?

When submitting the request for access to your treatment, your treating physician is required to share certain personal information about you with Novartis (hereinafter referred to as "your data/personal information").

Novartis solely receives information about your gender, month and year of birth and information about your health, such as your medical condition and the information about the treatment you have received so far. In case your treating physician requests a re-supply of the treatment for you, additional information about the treatment efficacy may also be requested. Other data, such as your initials, may be collected only if required by local laws or regulatory authorities. Novartis does not receive your directly identifiable information such as your name or address unless it is required for the shipment of your treatment as per the country requirements – in such case your name and contact details may be required for the shipment.

Novartis needs your data to:

- manage the request, e.g., evaluate your eligibility for the treatment
- manage the shipment: in countries where we are required to ship your treatment directly to you
- comply with legal or regulatory requirements, for example, in case of safety events.

Novartis may also further anonymize your data, which means that the data can no longer be linked back to you. Anonymized data may be used by Novartis for other purposes such as writing scientific publications and educational papers and may share it with others including external partners or health authorities.

Who can see your data?

Your data can be seen by:

- Institutional review boards or ethics committees
- Novartis and their representatives

- Third parties hired by Novartis to provide services related to the management of the request and other purposes outlined in this document,
- Health Authorities

The people and organizations listed in the section above are required to keep your data confidential. Novartis representatives and third parties hired by Novartis may be located in countries that do not provide the same level of data protection, however during the transfer of your data, Novartis will protect the privacy of your data by applying safeguards as required by law.

Novartis collects and uses your data based on your consent and to meet its legal obligations.

Novartis will retain your personal information only for as long as necessary to fulfil the purposes described in this notice and to meet applicable legal and regulatory requirements. Where required by law, certain information may be retained for longer periods, after which it will be securely deleted or anonymised.

What are your privacy rights?

Subject to applicable laws and regulations, including POPIA, you have the right to:

- ask to review and correct or erase your data;
- ask for a copy of your data;
- ask to get your data in a standard electronic format so you may transfer it to another organization (the law calls it 'right of portability');
- oppose the use or the use of part of your data on reasonable grounds;
- withdraw your consent, without affecting the lawfulness of our use of your data prior to such withdrawal; and
- lodge a complaint with the relevant data protection authority. In South Africa, you have the right to lodge a complaint with the Information Regulator (<https://inforegulator.org.za>).

Novartis may be restricted by law in following requests related to your privacy rights, it may e.g. not be possible to erase certain data, where data needs to be available for health authority or regulatory purposes.

If you have any questions about your data or want to exercise the above rights, please contact your treating physician.

You can also contact the Novartis data protection officer at the email address privacy.za@novartis.com or writing per post mail to "South Africa Data Privacy Officer, Midrand, Gauteng, 2066, South Africa".

If you reach out directly to Novartis, and not through your physician, Novartis may know your identity. In addition to the rights above, you may have the right under applicable law to file a complaint with the competent regulatory authority.

This form will be retained by your physician.

By signing below, I agree to the sharing and use of my data, as described in this privacy notice.

Typed/printed name of
Patient / Parent/Guardian

Signature

Date