

MANAGED ACCESS NOTICE AND CONSENT FORM

Processing of personal data

1. Introduction

Your treating physician is considering applying for managed access on your behalf. Managed access is a mechanism through which pharmaceutical companies can bridge a medicine's lifecycle gap, from development phase to commercial availability, by providing patients, with an unmet medical need, access to not yet commercially available medicines.

In order for your treating physician to be able to apply for managed access, and in order for Swedish Orphan Biovitrum AB ("Sobi") to be able to assess whether they can provide the medicine, your personal data will have to be shared with Sobi.

2. What is the purpose of the processing of your personal data?

In order for your treating physician to be able to apply for managed access, and in order for Swedish Orphan Biovitrum AB ("Sobi") to be able to assess whether they can provide the medicine, your personal data will have to be shared with Sobi. This notice provides information regarding the use of your personal data and your rights in relation to personal data, which is required by applicable data protection laws including the EU Regulation 2016/679 called the General Data Protection Regulation (GDPR).

3. What personal data is being processed?

Your physician will not share personal data with Sobi which allow for the direct identification of you, e.g. name and social security number. Your physician will however need to share some of your health data e.g. medical conditions, medical history, weight, and concomitant medication. Even though Sobi will not be able to immediately connect such data with you, the data qualifies as personal data under applicable legislation. Your consent provides the legal basis which allows Sobi to process your data for the above-mentioned purposes.

In addition to the processing of your personal data for the above-mentioned purposes, your personal data may also be processed for the purpose of complying with legal requirements, such as safety reporting. The legal base for such processing of your personal data is to comply with a legal obligation and, that processing is necessary for reasons of public interest in the area of public health (EU General Data Protection Regulation, "GDPR", article 6(1)(c) and 9(2)(i)).

4. How will your personal data be protected?

As the data controller, Sobi is responsible for the processing and safeguarding of your personal data and for ensuring that your rights under data protection laws are fulfilled. Your personal data will be treated in the strictest confidence. Sobi takes all reasonable measures to safeguard your personal data.

5. To whom will your personal data be transferred or disclosed?

Sobi will not transfer or disclose personal data received for the purposes of approving and enabling access to the medicine. In case of a managed access program/cohort program, Sobi may disclose personal data to regulatory authorities and Institutional Review Boards/ Ethics committees when providing reports. For managed access programs/cohort programs, Sobi may also issue scientific publications. Such publications will never contain personal data that directly identify you.

6. How long will your personal data be stored?

Your personal data will only be stored for as long as needed for the purposes described above unless a longer storage period is required for legal or regulatory reasons.

7. Transfer to countries outside the EU

Your personal data may be transferred to countries outside the EU, where the laws may not protect your personal data to the same extent as the laws in the EU/EEA. The purpose with such transfer is to review and approve that the medicine is provided for managed access purposes as well as for medicine distribution purposes. When your personal data is transferred to such countries outside the EU/EEA, the controller of personal data, Sobi, is responsible for taking reasonable steps to protect your personal data and keep it secure and confidential.

8. Your rights regarding your personal data

You may always withdraw your consent for processing of your personal data by contacting your treating physician. You may also contact Sobi by writing to sobi@privacy.com. However, since we do not know your identity, we may not be able to assist you without contacting your treating physician.

You have the right at no cost to access the personal data collected about you and ask for corrections of any inaccurate data. You may also request deletion of your data, and restriction on or objection to the processing of your personal data.

You have the right to complain about how your personal data is handled to your treating physician and/or Sobi. You also have a right to complain to a supervisory authority that is responsible for enforcing data protection law. For example, you can complain to the supervisory authority in the country where you live. You always have a right to complain to the supervisory authority in Sweden, the Swedish Data Protection Authority (Sw. *Integritetsmyndigheten*).

9. More information regarding your rights in relation to personal data

For more information regarding the processing of your personal data related to the managed access, please contact your treating physician, who will contact the sponsor's data protection officer if needed, or directly to Sobi's data protection officer by writing to privacy@sobi.com.

Name of treating physician

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Contact details to treating physician

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Consent form follows on next page

Consent to the Collection, Processing, and Use of Personal Data

By signing below, I agree that:

- (1) My personal data, including sensitive personal data, can be collected and used by Sobi for purposes of providing managed access as described in this notice and consent form, and
- (2) My personal data, including sensitive personal data, can be transferred to and shared with other companies both within and outside of the European Economic Area (EEA), including to countries that may not have the same level of data protection as the EEA, as described in this notice and consent form.

Patient name (print)

Patient signature

Date

NB! This notice and consent form is to be archived by the treating physician and not forwarded to Sobi.