PERSONAL DATA PROTECTION NOTICE

FOR ADVERSE EVENT, PHARMACOVIGILANCE & PRODUCT QUALITY REPORTING

Last Revised: v1.2 – 01 June 2023

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1. Introduction

1.1. Your personal data rights are important to **Novugen** (including subsidiaries, affiliates and associated companies, hereinafter collectively referred to as "**we**", "**our**" or "**us**").

1.2. That is why we have designed this Personal Data Protection Notice ("**Notice**") to provide transparency on how we process certain information that can be used to identify you (also known as "**personal data**") in compliance with the Malaysia Personal Data Protection Act 2010 ("**PDPA**") when you either:

- report a suspected adverse event ("**AE**") or product quality complaint (including reports you make on behalf of someone else) of products that we have marketing authorization for, or
- was identified in a report as an individual being impacted by a suspected AE or product quality complaint ("**patient**")

For examples of the type of personal data that we process, please refer to **[Types of Personal Data Collected]** below.

Please also note that "processing" generally means any operations done on the personal data, such as collection, use, storage, retention, or disclosure.

IMPORTANT! Please read this Notice carefully because by reporting a suspected AE or product quality complaint, you are agreeing and consenting to us processing personal data in accordance with this Notice, and you represent and warrant to us that:

- report and the contents (including personal data) that you submit to us is accurate, up-to-date, and complete, and
- in event you are disclosing personal data of another person to us, that you have provided a copy of this Notice to such other person, and you were authorized by such other person to disclose such personal data to us, and that such personal data is accurate, up-to-date, and complete.

1.3. **Additional Consent.** Please note that this Notice does not replace any other consents you may have previously or separately provided to us in respect of your personal data. Your consent to this Notice is in addition to any other rights which we may have at law to process your personal data.

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1.4. **Supplement Notice.** This Notice may be supplemented by supplementary notices for specific interactions, products, services, or jurisdiction. Please refer to our **[Privacy Centre]** for more information.

1.5. **Additional languages.** This Notice is further available in other languages. Please refer to our **[Privacy Centre]** for more information. In the event of any conflict, inconsistency or ambiguity between the English text of this Notice and other language translation thereof, the English text shall prevail.

1.6. If you are not sure whether this Notice applies to you, please **[Contact Us].**

2. Types of Personal Data Collected

2.1. The extent of and the exact personal data that are processed vary from case to case depending on a range of factors and circumstances, such as your role (whether as a reporter or patient), and the nature and severity of the report (e.g. AE or product quality complaint).

Below is an overview of the categories and example personal data that we may process in relation to the report received:

i. **Identification data** such as name, title, gender, date of birth, national registration identity card or passport number

ii. **Contact data** such as correspondence address, delivery address, e-mail address, fax number and telephone number

iii. **Audio-visual data** which you share. This may be provided to us when you share image, sounds or videos to us to us when supporting any reports.

iv. **any other data that you voluntarily share**

v. If you are a reporter, we may further request information about your **profession** and **relationship with the patient**. This information will assist us in identifying the extent of your knowledge pertaining to the suspected AE or product quality complaint, and determine the questions to be asked.

vi. If there is a patient identified to be affected by the suspected AE or product quality report, patient' **health data** that are relevant for said report. Examples of such data are:
- Patient's weight, height, and ethnic group
- previous and current health or medical condition
- details of the product suspected to cause the adverse reaction (including reasons of taking such product, and dosage and consumption period)
- details of the adverse reactions suffered, treatment received, and long-term effects the reaction has caused to your health
- details of other medicines or remedies that you took at the time of the adverse reaction (e.g., dosage, consumption period, reason you have been taking such other medicines or remedies, and any subsequent change to your regimen)

The provision of personal data to us is voluntary. The type of personal data we process, though may vary depending on the nature of transaction, will only be adequate and necessary for the purposes described herein. We will indicate when it is obligatory to provide the personal data to us to enable us to process your data in relation to specific purpose. If you decline to provide such obligatory personal data, we may not be able to fulfil the said purpose.

2.2. **Sensitive personal data**. Some of the data above may be considered by law to be "sensitive personal data". Sensitive personal data under the PDPA, for example, includes the following:

i. physical or mental health or condition

ii. political opinions
iii. religious beliefs or other beliefs of a similar nature,
iv. the commission or alleged commission offence

We do not seek to collect or otherwise process sensitive personal data in the ordinary course of our business. We only process sensitive personal data when:

v. it is upon your request, in which we rely on your prior explicit consent. For example, you may volunteer your physical or mental health or condition information when enquiring our products, or request us to investigate into your complaint or report, or

vi. it is permitted or required by the law. For example, we may be subjected to pharmacovigilance, safety, and any other legal requirements to take and keep detailed records of every AE so we (and relevant authority) can evaluate and make efforts to prevent similar events from happening in the future.

3. How is the Personal Data Collected

3.1. **Directly from you.** We collect personal data from you when you voluntarily report an AE or product quality complaint directly to us. This could be via AE reporting forms, questionnaires, and interviews.

3.2. **Indirectly from third-party sources.** Sometimes, we may receive information from other third-party sources. Overview of such third-party sources are:

i. Third-party that have reported a suspected AE or product quality complaint. This could include reports given by your family members, your attending doctor or other healthcare professionals, or distributors of our products.

ii. Third-party that you have authorized to act on your behalf, such as your caregiver or agent

iii. Government sources such as regulatory authorities, court, and enforcement officials

Such information may identify you (and as such be considered as personal data) but may also be in the form where it is aggregated and anonymized where it cannot identify you. Where it involves personal data, we take reasonable steps to ensure such third-parties were legally permitted to disclose such personal data to us.

3.3. Where permitted by the law, we may combine both the information you provide us and automatically collected information with other information collected from third-party sources.

4. Purposes Of Personal Data

4.1. The personal data we collect in relation to this notice will be used only for the specific purpose of these activities. The specific purposes of this processing are there to:

i. To investigate and manage any reports or complaints we received on suspected AE or product quality, including:
   - Contacting you for further information relating to the report
   - Responding to any other queries or requests you may have

ii. Fulfill legitimate business interest, including:
   - To assess, monitor and improve the performance, safety and quality of our products and services.

- To establish, pursue, exercise and enforce our rights, and further defend ourselves in any legal claims or proceedings which we may be involved in.

iii. For educational and scientific purposes, such as publishing AE case studies and summaries. However, in this case, we will strictly remove direct identifiers so that patient can't be recognized.

iv. To comply with the law (which includes regulatory requirements, industry standards and court orders) that we are subjected to. For example, to comply with record-keeping and reporting obligations in respect of AE and safety.

v. Fulfil any other purposes you requested for.

vi. Fulfil any other purposes permitted or required by the law, and are incidental to any of the purposes detailed in this Notice.

5. Disclosure & International Transfer of Personal Data

5.1. As a multinational company operating worldwide, your personal data may be disclosed, transferred, and processed for the purposes indicated in **[Purposes of Personal Data]** above to any of the following categories or classes of parties whether within or outside Malaysia:

i. **our personnel** and **members within our group,** including our affiliates and subsidiaries.

ii. **our external advisors** such as lawyers, accountants, company secretary, auditors, insurers and brokers.

iii. **our third-party providers.** Like many businesses, we may engage specialized providers that can help us serve you better, such as pharmacovigilance providers, call centre operators, data storage providers, technical support, et cetera

iv. **relevant government regulators or authorities, statutory boards, law enforcement agencies, industry regulators** or any person to whom we are compelled or required to do so under law. For example, where we are required to notify national health authorities or other health regulators about AE to our medicinal products, we will share personal data with them for that purpose. We are unable to fully control such authorities use of any information we share, however note that in these circumstances and provided allowed by the relevant law, we will only share pseudonymised information (such as patient's initials) and share information that directly identifies the patient (such as patient name or contact information).

v. **manufacturers, distribution and other license partners,** where pharmacovigilance obligations for a product require such exchange of safety information.

vi. **potential acquirers and other stakeholders** in the event of potential, proposed or actual business transfer, whether in whole or in part, sale of business, disposal, acquisition, merger, spin-off, joint venture, assignment, reorganisation of our business, assets or stock or similar transaction.

vii. **any other party to whom you authorize** us to disclose your personal data to. This may for example, include third parties (such as your attending doctor or other healthcare professional) that you have authorized to support you in lodging an AE or product quality report.

5.2. By interacting with us and/or providing personal data to us, you are consenting to any such transfer, disclosure, and processing of your personal data outside Malaysia. We will, however, endeavour that reasonable steps are taken by the above categories of parties to protect and/or maintain confidentiality of your information that we may disclose to them.

6. Your Choices & Rights

6.1. You have the following rights under the PDPA:

i. **Right to access your personal data.** You can obtain information on the processing of your personal data and to receive a copy these data

ii. **Rights to correct your personal data.** You can correct or complete your personal data to the extent it is inaccurate, incomplete, misleading or not up-to-date. You should keep keep us informed of any changes to your personal data.

iii. **Rights to limit the processing of personal data, or withdraw your consent.**

6.2. **[Contact Us]** if you like to exercise any of the above rights.

Please note that we value the security and confidentiality of personal data. Hence, for any request submitted, we will first verify the identity of the requester to ensure that the requester is either:

- legitimately the person about whom we collected the personal data, or
- authorized by the person about whom we collected the personal data

We verify every request carefully. You are encourage to ensure that request submitted has:

- sufficient details that allows us to reasonably verify you are the person about whom we collected personal data or an authorized representative, and
- sufficient details that allows us to properly understand, evaluate, and respond to it.

We will always aim to help you when you wish to exercise your rights but in some instances we may have lawful grounds to reject your request, such as when we cannot verify your identity to determine if the requested personal data relates to you, or when there is an existing legal or contractual basis, or where permitted by the relevant law.

We will investigate any request you make promptly and will respond to you within the timelines provided by the PDPA. Kindly note that period may be extended where this is needed to help us respond properly (e.g. if the request is complicated for us to deal with and we need more time) but we will let you know the reasons for the delay.

Fees. Kindly note as permitted under the PDPA or relevant law, we may charge a reasonable fee if your request, particularly where the request is complex, or otherwise repetitive or excessive.

6.3. **Specific Rights.** In some applicable jurisdictions, you may have certain rights under relevant data protection laws. Please see the addendum to this Notice for specific additional information by region/country in the **[Privacy Center]**. Alternatively, you may **[Contact Us]**.

7. How do we secure & protect your personal data?

7.1. **Our safeguards.** We will use reasonable endeavour to protect personal data in our possession or control against risks of loss, misuse, unauthorized or accidental access or disclosure, unauthorized collection, use, copying, modification, disposal or destruction, through reasonable and appropriate security measures. We strive to ensure that our systems are secure and meet industry standards. To prevent unauthorized access, we have put in place appropriate physical, electronic and managerial procedures to safeguard and secure the personal data we collect.

7.2. **Your responsibilities.** Despite our security measures, please note that no method of transmission over the Internet or method of electronic storage is completely secure or error free. Safeguarding and protecting personal data is a shared responsibility. You play an important role in protecting and safeguarding your personal data. It is your responsibility to employ adequate safeguards such as:

- using a secure web browser
- have adequate passwords (if any), and maintain the secrecy of your password
- ensure that the electronic device you are using is adequately secured and protected against malicious software, such as trojans, computer viruses and worm programs. Such security includes up-to-date anti-virus software and firewall
- do not use, access or download of files or software from dubious sources
- always log-out, and do not have your email address and password remembered if you are using a shared or public electronic device

You are aware of the fact that without adequate safeguards there is a risk that your personal data could be disclosed to unauthorized third-parties from your end.

8. How long is the personal data kept?

We may retain your personal data for as long as it is necessary to fulfil the purpose for which it was collected, or as required or permitted by the PPDA. We will cease to retain your personal data, or remove the means by which the data can be associated with you, as soon as it is reasonable to assume that such retention no longer serves the purpose for which the personal data was collected, and is no longer necessary for legal or business purposes.

9. Updates To This Notice

From time to time, we may amend this Notice for various reasons, for example:

i. to improve this Notice, such as changing the design or look of the Notice, or adding clarification where required, or correcting inadvertent errors,
ii. to accurately reflect our data handling practices,
iii. to reflect new developments on products, services, or other technological advancement, and
iv. to comply with changes with the applicable law, regulatory requirements, and industry practices.

The amended Notice will be effective on the posting date detailed above.

We will notify you of the amended Notice by displaying prominently on our website at **www.novugen.com** ("**Site**") that there are amendments to the Notice.

Your continued interaction with us or sharing of your personal data with us on or after the display of the amended Notice on the Site indicates your consent to the process your personal data as per the amended Notice.

You are responsible to periodically review the Site for the latest information on our data handling practices.

10. Contact Us

If you have any queries about this Notice or our data handling practices, please contact our data privacy officer at the following:

- Email : **privacy@novugen.com**
- Phone : +603 5870 2242

Change Log / History

Revision No. & Date	Remarks
v 1.0 7 June 2022	Online publication of Notice.
v 1.1 21 December 2022	Fixed inadvertent spelling error to resulting to broken links to Privacy Centre.
v 1.2 01 June 2023	Amended the words “Novugen Pharma Sdn Bhd” in Section 1.1 to “Novugen”