



Privacy Notice for Handling of Adverse Events

(Handling of Adverse Events)

1) Scope of This Policy

This Personal Data Protection Policy is established to protect your personal data and privacy. The Company processes personal data responsibly and in compliance with the Personal Data Protection Act B.E. 2562 (2019) and other applicable laws.

This notice applies to users of products and services of **Pacific Healthcare (Thailand) Co., Ltd.** (“the Company”), healthcare professionals, other experts, and any individuals involved in activities related to the **handling of adverse events**, including:

Reporting safety information, adverse events, undesirable effects, or malfunctions related to health products to the Health Product Vigilance Center, Thai Food and Drug Administration, Ministry of Public Health and/or the manufacturer, as applicable to each product category, in order to comply with applicable laws, regulations, and requirements both locally and internationally under the framework of health product safety surveillance

2) Personal Data Collected by the Company

2.1 Definitions and Examples of Data Collected

Personal Data	Personal details of the reporter and/or patient, such as title, first name, last name (Thai/English), gender, date of birth, age, national ID number, weight, height, etc.
Sensitive Personal Data	Special categories of data under Section 26 of the PDPA, including but not limited to race, health data (medical diagnosis, medication history, underlying diseases, allergy history, product usage), sex life, disability status, health risk factors, biometric data, etc.
Contact Information	Contact details of the reporter and/or patient, such as mobile phone number, email address, contact address, event location, workplace phone number, fax number, and places where the event occurred (e.g., hospital, clinic, organization, company).
Professional Information	Details of the reporter’s professional qualifications, such as occupation, position, education level, etc.
Anonymized Data	Personal data that has been processed so that it cannot identify an individual, e.g., a reporter named “Mrs. Somjai Jaidee” may be referred to as “Ms. SJ” when information is shared with the product manufacturer.
Other Information	Records of correspondence and communication between you and the Company, including product usage-related information beyond the categories above.



Processing Activity	Personal Data	Sensitive Data	Contact Data	Qualification Data	Anonymous Data	Other Data
1. Reporter information and/or patient information collected and stored by Pacific Healthcare (Thailand) Co., Ltd.	✓	✓	✓	✓	✓	✓
2. Reporter information and/or patient information submitted to the manufacturer to comply with applicable laws and regulations (EU and worldwide) under the framework of pharmacovigilance	✓	✓	✓ <i>(only data related to the location where the incident occurred)</i>	✓	✓	✓
3. Reporter information and/or patient information submitted to the Health Product Safety Monitoring Center, Thai FDA, Ministry of Public Health, and relevant regulatory authorities within the country	✓	✓	✓	✓	✓	✓

2.2 Sources of Personal Data

2.2.1 The Company obtains your personal data directly from you, whether in electronic form or hard copy, through communication channels between you and the Company in any form or method. This includes, but is not limited to, telephone, email, fax, messaging, the Company’s website, or through contact with sales representatives or employees in any position within the Company.

2.2.2 The Company obtains your personal data from other sources, including but not limited to publicly accessible sources, from your patients (in cases where patients inform the Company that you are their healthcare provider), and from patient organizations, including when you mention the Company online, such as referring to the Company’s products on social media, etc.



3) Purposes of Personal Data Processing and Legal Basis

Processing of personal data	Purposes of data processing	Legal Basis
<ol style="list-style-type: none"> 1. Reporter information and/or patient information collected and stored by Pacific Healthcare (Thailand) Co., Ltd. 2. Reporter information and/or patient information submitted to the manufacturer in order to comply with applicable laws and regulations (in the European Union and worldwide), within the framework of pharmacovigilance (monitoring the safety of healthcare products). 3. Reporter information and/or patient information submitted to the Health Product Safety Monitoring Center, Food and Drug Administration (FDA). 	<p>To improve products and to protect patients and consumers: The Company will use the information you provide to analyze and better understand the impact that the products have on you and/or your patients, in order to monitor and address safety concerns, as well as to further develop and improve the products distributed by the Company. The Company may also use your information to inform you of actions taken in relation to the impact that the products have on you and/or your patients.</p> <p>To comply with legal obligations / protection: The Company will use the information you provide to fulfill its monitoring and reporting obligations as required by law, including but not limited to activities related to adverse event reporting, which may be associated with handling customer complaints (Customer Complaint) or responding to medical information inquiries (Medical Inquiries), providing information related to consumer safety, and/or other matters that may pose serious risks (such as preventing harm to life, body, or health of individuals). The Company reserves the right to collect and use your personal data as required by law when it believes that such collection and/or use is necessary to comply with legal processes, court orders, or legal proceedings involving the Company, or to protect the safety, rights, or property of customers, the public, or the Company.</p>	<p>Legitimate Interest</p>



4) Disclosure of Personal Data

The Company may disclose your personal data under lawful processing bases as follows:

- **Legal Obligation:** Disclosure to government authorities and regulators.
- **Legitimate Interest:** Use and disclosure by the Company and disclosure to product manufacturers related to reported adverse events, while maintaining a balance between the Company's legitimate interests and your privacy rights to avoid undue impact on your fundamental rights and freedoms.

5) Cross-Border Transfer of Personal Data

The Company conducts business with manufacturers both within Thailand and internationally. As such, the Company may need to transfer and process your personal data outside of Thailand, the location where the data was originally collected. These countries include, but are not limited to, China, India, Korea, France, Spain, Italy, and the Netherlands.

The Company implements appropriate measures to protect your personal data when it is transferred outside Thailand. However, data protection laws in the countries to which your personal data is transferred may differ from those applicable in Thailand. In addition, law enforcement authorities, regulatory bodies, security agencies, or courts in these countries may have the right to access your personal data.



6) Retention and Storage of Personal Data

The Company retains your personal data as follows:

6.1 Storage and Location

The Company stores personal data according to its nature, as follows:

- **Hard Copy Data:** Personal data in physical document form is stored in secure locations within the Company's premises, such as locked filing cabinets with controlled access rights.
- **Electronic Data:** Personal data is stored in the Company's centralized database system, which is maintained with appropriate security measures and access control to ensure protection and confidentiality.

Note:

- 1.) Printed documents (Hard Copy) received from you through any communication channel between you and the Company, regardless of format or method, including but not limited to telephone, email, fax, messaging, the Company's website, or contact with sales representatives or employees in any position within the Company. The Company scans and stores these documents in the Company's document and electronic data management system (Electronic), which is maintained in the Company's central database with security measures to protect the data (Security) and includes defined access rights to the data (Access Control).
- 2.) Electronic documents received from you are stored in the Company's document and electronic data management system (Electronic) within the Company's central database. The system is managed with data security measures (Security) and includes defined access rights to ensure controlled access to the data (Access Control).

6.2 Retention Period

Personal data will be retained according to the purposes of data processing for a **period of 10 years** from the expiration or withdrawal of the product registration related to the defective product reported by you, or related to the medical inquiries received from you, as regulated by the relevant Thai authorities. After this period, the data will be archived or deleted. Please note that such data may be retained longer if required by other applicable laws.



7) Rights of Data Subjects

You have the following rights:

1. Right to withdraw consent
2. Right to be informed
3. Right of access
4. Right to rectification
5. Right to erasure
6. Right to restriction of processing
7. Right to data portability
8. Right to object
9. Right to lodge a complaint

You may contact the Company's Data Protection Officer (DPO) to exercise any of the above rights (contact details are provided in the "Contact Information" section below). You may also review details regarding the conditions and exceptions to exercising these rights at the Ministry of Digital Economy and Society website: <http://www.mdcs.go.th>.

Please note that there is no charge for exercising your rights. The Company will consider and respond to your request within 30 days from the date of receipt. If your request is denied, the Company will notify you of the reasons via your preferred contact channel. Should you have any questions or further complaints related to your request, please feel free to contact the Company's Data Protection Officer (DPO).

8) Changes to This Privacy Policy

The Company will regularly review this privacy policy to ensure compliance with best practices and applicable laws and regulations. If there are any changes to the privacy policy, the Company will notify you by updating the information on the Company's website as soon as possible.



However, the Company recommends that you regularly review the policy updates, especially before providing any personal data to the Company. Continued use of the Company's products or services after changes have been posted on the website will be considered as your acceptance of such changes.

Contact Information

Data Controller

- **Thai Name:** Pacific Healthcare (Thailand) Co., Ltd.
- **English Name:** Pacific Healthcare (Thailand) Co., Ltd.
- **Address:** 1320 CYAM Park Building, Unit B 01, 1st and 2nd Floor, Rama 3 Road, Chongnonsee, Yannawa, Bangkok 10120, Thailand
- **Tel:** 02-881-2488
- **Website:** <https://www.phc.co.th/>
- **DPO Email:** pdpa@phc.co.th