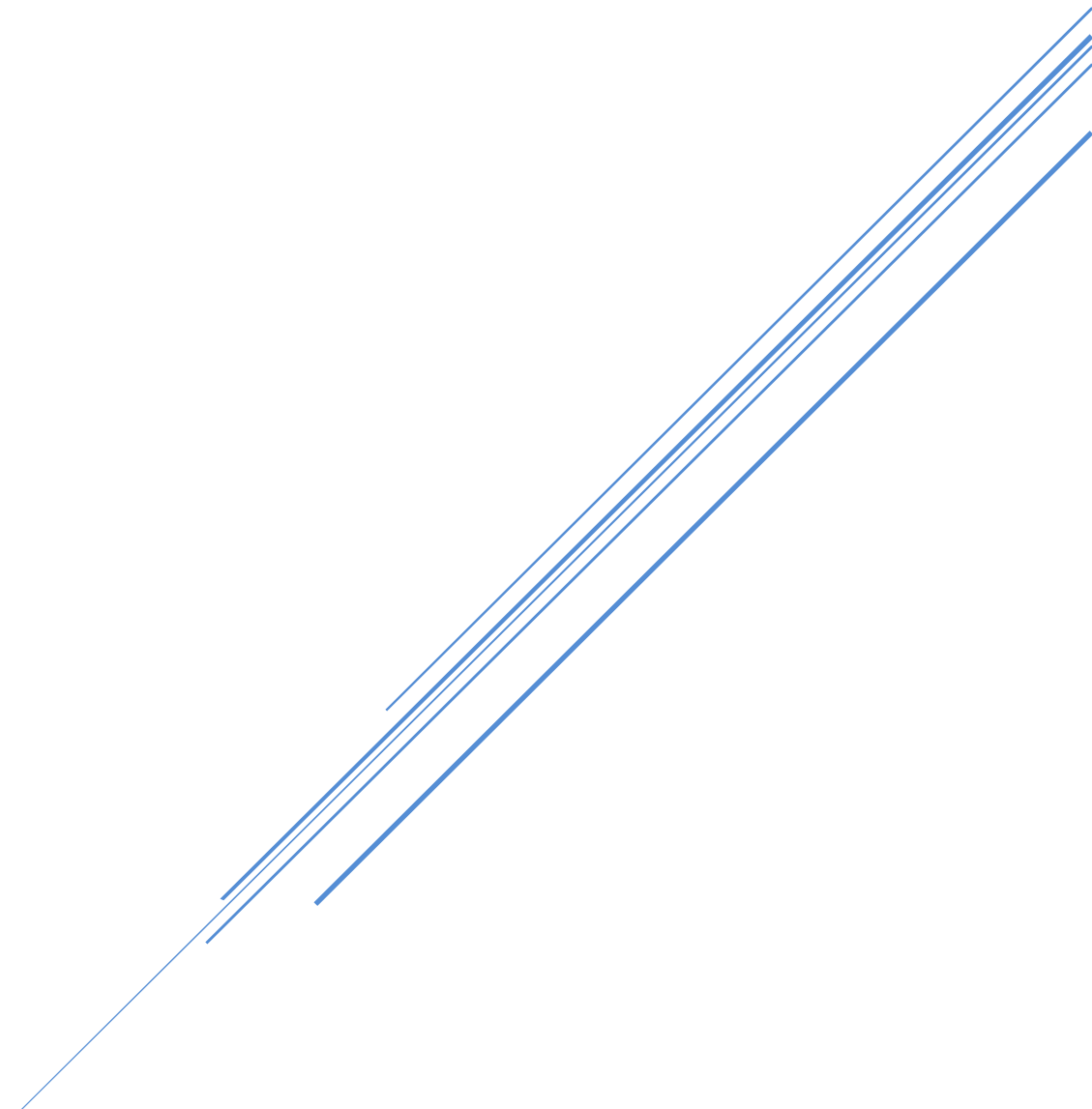




# ER-KIM EUROPE POLICY

## DATA PRIVACY POLICY





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## 1. INTRODUCTION

At Er-Kim Pharmaceuticals, we are committed to the responsible use of Personal Information in our business processes and the setting of the appropriate standards to achieve this purpose. To that end, we have developed the privacy principles below to be applied to the processing of Personal Information in daily activities by all Er-Kim Europe Affiliates.

## 2. DEFINITION

**"AFFILIATE(S)"** means any person, firm, trust, partnership, corporation, company or other entity or combination thereof which directly or indirectly (a) controls Er-Kim Pharmaceuticals, (b) is controlled by Er-Kim Pharmaceuticals, or (c) is under common control with Er-Kim Pharmaceuticals;

**"ANONYMIZATION"** means the process by which Personal Information is irreversibly stripped of all identifiers and can no longer be linked back to the person. Once this is done, it is no longer considered Personal Information.

**"CONSENT"** means any freely given, specific, revocable and informed indication of the person's agreement to the processing of his/her Personal Information.

**"CONTROL"** means the possession, directly or indirectly, of the right or power to direct or cause the direction of the management policies of a party either by contract, by ownership of shares or securities carrying a majority of the votes, by the ability to appoint the majority of the directors or other governing officers of a Party, by ownership of shares or other securities which carry the right to receive the greater part of the income or assets of such party or by any other means, and the terms 'Controlled by', 'Controlling' and 'under common Control with' shall have correlative meanings

**"DATA CONTROLLER"** means the natural or legal person which, alone or jointly with others, determines the purposes and means of the processing of Personal Information.

**"DATA PROCESSOR"** means the natural or legal person, which Processes Personal Information on behalf and under the instructions of the Data Controller.

**"DATA SUBJECT"** means the identified or identifiable natural (and, in some jurisdictions also legal) person whose Personal Information is Processed; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity (including a social security number or a code in a clinical trial case report form in combination with other information).

**"DISCLOSURE / DISCLOSE / DISCLOSED"** means making Personal Information accessible to any person or company other than the Data Subject, the Data Controller or Data Processor. This may include but is not limited to the active Transfer of Personal Information to all Er-Kim Affiliates or third parties, permitting access (including remote access), distribution or publication.

**"ER-KIM PHARMACEUTICALS"** means Er-Kim Turkey together with companies Controlled by, Controlling or under common Control with Er-Kim Turkey.

**"ER-KIM EUROPE AFFILIATES"** means Er-Kim Sanayi ve Ticaret Anonim Şirketi ("Er-Kim Turkey")'s Affiliates in the European Countries..



**“EXPLICIT CONSENT”** means that a Data Subject is clearly presented with an option to agree or disagree with the collection, use, or disclosure of Personal Information and clearly indicates their choice.

**“HEADQUARTER”** means Er-Kim İlaç Sanayi ve Ticaret Anonim Şirketi operating in Istanbul/Turkey.

**“LEGITIMATE BUSINESS PURPOSE”** means a purpose which is directly or indirectly related to the business operations of Er-Kim Pharmaceuticals and which does not interfere with the fundamental rights and freedoms of the Data Subject. For example, HR managers may process Personal Information to perform their administrative obligation. A Legitimate Business Purpose may include compliance with legal, regulatory or ethical obligations applicable to the company.

**“PERSONAL DATA SECURITY INCIDENT”** means (a) the loss or misuse of Personal Information, (b) the accidental, unauthorized and/or unlawful access or handling of Personal Information, or (c) any other act or omission that compromises the security, confidentiality and/or integrity of Personal Information.

**“PERSONAL INFORMATION”** means all information that relates to a person where that person can be identified by you or others. In some cases, the person can be identified directly (e.g., your name or your photograph) or the person can be identified indirectly (e.g., a medical insurance number, your position in a company or by means of a study code assigned in a clinical trial). In some countries, Personal Information may also include information such as medical device serial numbers, biological samples, IP addresses or information relating to a company (“legal person”). The definition of Personal Information may vary by country and local law should be consulted. Affiliates should check with the Headquarter for guidance.

**“PRIVACY NOTICE”** means an oral or written statement that Data Subjects are given when Personal Information about them is being collected. The Privacy Notice describes who is collecting Personal Information, why Personal Information is being collected, how it will be used, shared, stored and any other relevant information of which the person should be aware. Oral notices may need to be recorded to establish evidence that notice was provided to the person and these requirements should be stated in local SOPs, if applicable.

**“PROCESS / PROCESSING / PROCESSED”** means any operation or set of operations performed upon Personal Information. This definition includes, but is not limited to, collection, recording, organization, storage, retrieval, use, disclosure, Anonymization, Pseudonymization or deletion.

**“PSEUDONYMIZE”** means replacing a person’s name and most other identifying characteristics with a label, code or other artificial identifiers in order to protect against identification of the person.

**“SENSITIVE PERSONAL INFORMATION”** is a subset of Personal Information that requires a higher level of protection. Such information may include racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, social security or insurance information, criminal charges, conviction / sentence, or a person’s sexual orientation, or health information. Data elements that make up Sensitive Personal Information may vary by country and local law should be consulted. Affiliates should check with the Headquarter for guidance. Personal Information related to health is always considered as Sensitive Personal Information at Er-Kim.

**“THIRD PARTY”** is any person, including a legal entity, with whom Er-Kim Pharmaceuticals interacts and that is not an Er-Kim Pharmaceuticals company or Affiliate.



“TRANSFER” means any Disclosure of Personal Information by someone other than the person to whom the Personal Information belongs. The term “Transfer” may include the physical movement of Personal Information or the provision of access to Personal Information.

### 3. SCOPE AND APPLICABILITY

This Policy applies to all Er-Kim Europe Affiliates as well as to all Processes of Personal Information on behalf of Er-Kim Pharmaceuticals. Each Affiliate is accountable for compliance with Data Privacy obligations. This Policy sets the global privacy standards for Er-Kim Pharmaceuticals.

In addition, all Processing of Personal Information must be conducted in accordance with relevant local laws, regulations and industry codes, which may be more stringent than the requirements outlined in this Policy.

Affiliates manage Personal Information entrusted to Er-Kim Pharmaceuticals by patients, consumers, healthcare professionals, customers, employees and others on a daily basis. For example;

EMPLOYEES ORGANIZATION	& Employee benefit programs, pay, talent management, and recruitment activities. Employees’ Personal Information for the management of Personnel administration, performance review, and workplace monitoring.
FINANCE & PURCHASING	Employees’ Personal Information for the management of expense reports or cost centres. Vendor and spend data, contracts and assessments managed by purchasing.
MARKETING, MEDICAL	Market Research, development and provision of programs such as Patient Support Programs, social media listening, email communications, newsletters, mobile applications, other digital platform, and analytics
SALES	Interactions and communications with Healthcare Professionals to establish and maintain effective relationships
MEDICAL	Engagement of healthcare professionals, scientific experts and key opinion leaders for medical education program development, medical conferences and other events
MARKET ACCESS	Conducting health outcome analysis with assistance of patient-derived Personal Information
COMMUNICATIONS	Interactions with patients



CLINICAL OPERATIONS	Clinical trials and studies
RESEARCH	Early development of new medicines, biomarkers and innovations using human biological samples, genetic data or data from clinical trials and/or biobanks

#### 4. PRINCIPLES

Data Privacy is receiving increased societal attention and scrutiny, it is an emerging field of law with varying local maturity and evolving interpretation by the courts. We therefore need to apply a principles based approach to our decision making. All Processing of Personal Information shall comply with the five (5) fundamental principles as set out below. The five (5) principles are embedded in our commitment to abide by a high standard of ethical business conduct:

- Transparency
- Legitimate and Meaningful Collection
- Responsible and Sustainable Processing
- Security, Integrity and Quality
- Minimal Retention

At the back of each principle examples are given to illustrate how the principles can be generally applied - please note that, depending on the context, other mandatory elements may need to be considered.

##### a) TRANSPARENCY

We are transparent about what Personal Information we Process, how and why we collect it, use it, and who we share it with. We explain this in clear and simple language.

A fundamental principle of Data Privacy is that organizations must be open and transparent about how they manage the Personal Information they are entrusted with. This important principle both enhances our accountability for our practices in handling Personal Information and builds trust and confidence in these practices amongst our Affiliates, vendors, customers, HCPs, patients and stakeholders.

Er-Kim Europe Affiliates must:

- Provide information to Data Subjects about how their Personal Information will be used by Er-Kim at the time we collect the Personal Information (if practicable), or as soon as possible afterwards. This can be communicated in different ways, such as by providing Privacy Notices, Consent forms and/or privacy policies, on websites, or in printed materials when appropriate. Regardless of the form it takes, the information provided should be concise, transparent and written in clear and plain language.



- Focus on what is important for the Data Subject to know, and provide specifics about the handling of and type of Personal Information. The information should accurately and completely reflect the actual use of the data. For example, a notice for the collection of Sensitive Personal Information, such as health information, is likely to be more detailed than a notice on the collection of contact information. The Headquarter can help you develop a notice appropriate to the circumstances.

#### **b) LEGITIMATE AND MEANINGFUL COLLECTION**

We connect all collection and use of Personal Information to specific business purposes related to how we operate, innovate or engage.

We will only collect Personal Information if we have specific and legitimate reasons or requirements to do so. We only collect the minimum amount necessary for specific purposes. By not collecting more data than is required or needed we reduce the risks related to the Processing of the Personal Information. By limiting our collection to specific purposes we demonstrate a responsible use of the Personal Information entrusted to us.

Er-Kim Europe Affiliates must:

- Identify the business objective and legitimate reason for collecting Personal Information. The Headquarter can advise on the legal grounds for the collection of Personal Information.
- Explore whether alternatives to collecting Personal Information may be available to meet the specific purpose.
- Ensure that the Processing of Personal Information is only done to meet the identified business objective and legitimate reason (e.g., a legal requirement to manage handling of adverse events).
- Only collect the minimum amount of Personal Information needed for the specific purpose.
- Understand and recognize that there may be additional Data Privacy requirements when Processing Sensitive Personal Information.

#### **c) RESPONSIBLE AND SUSTAINABLE PROCESSING**

We use Personal Information only in ways compatible with the purposes for which it was collected. We facilitate Data Subjects to exercise their rights with regards to their Personal Information.

Responsible management of Personal Information is required to protect privacy rights and comply with Data Privacy laws. This includes ensuring that we only Process Personal Information we have collected for the original purposes for which it was collected, or for secondary uses that are appropriate. In doing so, we will meet our Data Privacy obligations and strengthen the trust of Data Subjects who entrust us with their data.

Er-Kim Europe Affiliates must take appropriate steps to:

- Use Personal Information only for specific business purposes described in the Privacy Notice, with specific legitimate justifications.



- Ensure that if Personal Information is collected for particular purposes, it can only be used for an additional secondary purpose if there is a legitimate justification. Such justification may include, where allowed, the conduct of a compatibility test, the collection of additional Consent from the Data Subject, or the applicability of additional safeguards, such as Pseudonymization. Before any secondary use of information, such as for research and statistical purposes, Affiliates must seek advice from the Headquarter.
- Prevent the use of Personal Information for a purpose that is not compatible with the original purpose it was collected for, or another legitimate secondary purpose.
- Discuss with the Headquarter before you share Personal Information with Third Parties.
- Obtain assurances from third parties who Process Personal Information on Er-Kim Pharmaceuticals' behalf that they have the ability and intention to protect Personal Information to the appropriate standard in accordance with this Policy and local data privacy requirements. This assurance could take the form of a contract which includes relevant Data Privacy terms and Processing instructions.
- Follow relevant local procedures for any legal requirements when transferring Personal Information across country borders. We have implemented mechanisms which in most circumstances allow internal data transfers of Personal Information within Er-Kim Pharmaceuticals. Affiliates may need to provide specific notice to the Data Subjects whose Personal Information is being transferred, and in certain cases the transfer may require their Consent. In some instances we may also need to notify a local data protection authority, or put in place contractual safeguards to protect the Personal Information. The Headquarter will support you in assessing and reviewing any risks relating to such sharing.
- Take into account these privacy principles at all stages when developing and designing products, services and applications and ensure that, by default, only Personal Information which are necessary for each specific purpose of the Processing are being Processed.
- Consult the Headquarter when Personal Information is Processed which is leading to an automated decision that affects an Data Subject.
- Implement or apply existing processes to ensure an appropriate and lawful response is given to Data Subjects who wish to exercise their legal rights (e.g., access, or deletion). Affiliates should consult the Headquarter to understand what rights are applicable in their country, and to discuss how to facilitate the exercise of these rights.

#### **d) SECURITY, INTEGRITY AND QUALITY**

We protect Personal Information by using reasonable safeguards to prevent its loss, unauthorized access, use, alteration or unauthorized disclosure, and take appropriate steps to keep Personal Information accurate and up to date.

Er-Kim Pharmaceuticals is entrusted with Personal Information and is responsible for taking reasonable steps to protect that information from misuse, interference and loss, as well as unauthorized access, modification or disclosure. The nature of the Personal Information, and the risk of a security incident occurring, will guide the level of protection. Sensitive Personal Information requires a higher standard





of protection. Security measures may be physical, such as locks and access cards for buildings, electronic, such as encryption and passwords, or organizational, such as restricting access to information to only those who need it. To ensure the initial accuracy of data and to maintain its integrity and quality, we need to regularly verify that the information is accurate and up to date.

Affiliates must:

- Take appropriate steps to keep Personal Information accurate and up to date through the information lifecycle, i.e. from collection through to destruction. For example, Data Subjects could be provided with a simple means to review and update their Personal Information on an on-going basis, and new or updated Personal Information is promptly added to a relevant record or database.
- Safeguard Personal Information so that it is not shared with others who do not have a valid business reason to access the information (sometimes referred to as a 'need to know' rule). For example, there would likely not be a valid reason for identifiable clinical research data to be shared with marketing Affiliates for marketing purposes.
- Report any actual or suspected Personal Data Security Incident, including loss or unauthorized access, to the IT Service Desk.
- Comply with Er-Kim Information Security policies and guidelines when Processing Personal Information such as implementing encryption, restricted-access to electronic folders and restricted-access rooms, applying a clean desk policy and securely destroying documents. Additional organizational or technical safeguards should also be considered.
- Consider, with the assistance from the Headquarter, whether to Anonymize or Pseudonymize (see definitions in the attached Privacy Glossary) the Personal Information as an appropriate security measure.

#### **e) MINIMAL RETENTION**

We keep Personal Information only for as long we can legitimately use it.

When Er-Kim Pharmaceuticals collects Personal Information, we do so for specific purposes which we communicate to Data Subjects. Once we have fulfilled such purposes, we may no longer have a lawful reason to continue to hold on to the Personal Information. Unless there is a legitimate reason and legal basis to keep or use the Personal Information for secondary purposes, we should no longer keep that Information.

Affiliates must:

- Keep Personal Information only as long as necessary for the specific purpose or as required by law. Consult your records retention schedules for specific timeframes for maintaining Personal Information.
- Ensure Personal Information collected and Processed remains necessary for the initial intended purpose and legitimate reason.



- Anonymization can be used as an alternative to deletion in some circumstances to drive further value from the data. Discuss with the Headquarter if you are considering Anonymizing Personal Information.

## **5. IMPLEMENTATION**

### **a) TRAINING OF THIS POLICY**

Affiliates must familiarize themselves with this Policy. Each Employee must participate in mandatory and role-based training that may be given. Employees should be invited to participate in role-specific trainings and in bi-annual e-learning courses by relevant Affiliate.

### **b) THIRD PARTIES**

Affiliates contracting Third Parties are ultimately responsible for how Third Parties conduct these activities on behalf of Er-Kim Pharmaceuticals. The best way to ensure responsible data use by Third Parties is to strictly follow the Procurement process which includes a Third Party risk assessment, and use of appropriate contractual language.

### **c) BREACH OF THIS POLICY**

Failure to comply with this Policy may lead to disciplinary and other actions, up to and including termination of employment.

### **d) LOCAL PROCEDURES**

If required due to more stringent local laws or regulations, Country organizations should implement this Policy through local functional procedures that can take the form of Standard Operating Procedures ("SOP"), guidance, procedures, or other appropriate controls. The local procedures must be reviewed periodically or ad hoc to comply with changes in local laws, and updated as necessary. Each Affiliate is responsible for coordinating the development and distribution of such SOPs, guidance, procedures or other controls to its own region.


**APPENDIX 1 DOCUMENT HISTORY AND VERSION CHECK REGISTRATION**

<b>Document Name</b>	Data Privacy Policy
<b>Writer</b>	Bilge KIYAK, Legal & Compliance Manager
<b>Approver</b>	CEM ZORLULAR, Board Chairman
<b>Publisher</b>	Ahu ÖZGÜR, Quality Manager
<b>Approval Date</b>	May 9th, 2022
<b>Review Date</b>	May 8th, 2024
<b>Review Period</b>	2 years
<b>Next Review Date</b>	May, 2026

<b>Version No</b>	<b>Version Date</b>	<b>Revision Details</b>
00	July 27 <sup>th</sup> , 2021	Data Privacy Policy, First Publish
00	May 9 <sup>th</sup> , 2022	The numbering system has been changed in accordance with DK-2022-0001. Data Privacy Policy has been revised in line with new format
01	May 8 <sup>th</sup> ,2024	Data Privacy Policy has been reviewed and revised.