BİLİM İLAÇ SANAYİİ VE TİCARET ANONİM ŞİRKETİ PRIVACY NOTICE ON ADVERSE EVENT / ADVERSE REACTION REPORTING WITHIN THE SCOPE OF PHARMACOVIGILANCE ACTIVITIES

1. Data Controller

Your personal data are processed by Bilim İlaç Sanayii ve Ticaret Anonim Şirketi, a joint stock company registered at Istanbul Trade Registry Directorate with the registration number of 79251-0 and having its registered office situated at Kaptanpaşa Mah. Zincirlikuyu Cad. No: 184 Beyoğlu / İstanbul (the "Company"), in its capacity as a data controller, in accordance with the provisions of the Law No. 6698 on the Protection of Personal Data (the "LPPD") and pursuant to this Privacy Notice on Adverse Event / Adverse Reaction Reporting within the Scope of Pharmacovigilance Activities (the "Privacy Notice").

Our Company respects your rights regarding your privacy and the protection of your personal data, and aims to establish and maintain a relationship with your party that is based on trust. Within this scope, our Company processes your personal data in accordance with all legal regulations on the protection of personal data, particularly the LPPD, and adopts all security measures which are required to ensure the security of your data. This Privacy Policy is intended to provide clarifications on the scope of processing of your personal data which are collected within the framework of the pharmacovigilance activities which are conducted by our Company for ensuring of patient security. For further details on the processing of your personal data by our Company, please visit Bilim İlaç Sanayii ve Ticaret Anonim Şirketi's Policy on the Protection and Processing of Personal Data, which is accessible from https://www.bilimilac.com.tr/en/protection-of-personal-data

This Privacy Notice is also applicable to the pharmacovigilance activities carried out by our Company in relation to the pharmaceutical products pertaining to our group company Hüsnü Arsan İlaçları A.Ş. as well as our contract manufacturing business partners and other contracted business partners, in addition to the pharmacovigilance activities carried out in relation to the pharmaceutical products pertaining to our Company.

2. The Methods of Collection of Your Personal Data

Your personal data are collected by our Company wholly or partly by automated means or provided that the process is a part of any data filing system, through non-automated means, from physical and/or electronic environments, via the reporting made to our Company (since, in principle, all pharmacovigilance-related reports are devised to be made to the Patient Safety Department which conducts the pharmacovigilance activities, please use one of the pharmacovigilance reporting methods which are also listed in this Privacy Notice), the reporting form available on our website (please use the specific field for pharmacovigilance reporting and fill in the relevant form and do not use the other request / complaint / reporting channels for such reporting), our Company's call center (the specific pharmacovigilance number should be pressed here for all pharmacovigilance reporting), printed forms, cargo/mail, complaint platforms – if complaints are communicated through such channels and social media platforms.

3. <u>The Categories of Your Processed Personal Data and the Purposes for and the Legal Basis of the Processing of Your Personal Data</u>

Your personal data categories which are processed within the scope of the conducting of the elimination of risks and/or risk minimization activities including the detection, assessment, identification and prevention by our Company of adverse reactions (side effects) / special situations (e.g. use during pregnancy or breastfeeding, overdose, off-label use, lack of efficacy, misuse, accidental exposure,

occupational exposure, abuse, transmission of infectious agent, suspicion of counterfeit pharmaceuticals, drug interactions, withdrawal symptoms) and other medicine-related problems which may arise during the use of the medicinal product by the pharmaceutical companies, and if necessary, the recall thereof from the market; the fulfillment of the applicable statutory obligations, particularly the pharmacovigilance activities which are conducted in order to ensure the follow up of incidents / adverse reactions and the proper operation of public health preventive activities, and thereby the conducting of the activities in accordance with the legislation; the furnishing of information and reports to the authorized individuals, institutions and organizations, particularly the authorized health organizations; the management of communication, audit and reporting activities for compliance with the policies and procedures of our group companies and the conducting of storage and archiving activities; and the purposes for and the legal basis for the processing of your personal data are thoroughly explained herein below.

N.B.: Please report adverse reaction (unexpected harmful effect / side effect) special situations in accordance with the applicable legislation enacted by the Ministry of Health, in particular – the Guidelines on the Protection of Personal Data in Pharmacovigilance Activities. If and when so required - the reporting is made by a relative or healthcare professional instead of the individual experiencing the adverse event; please communicate the name and surname of the individual experiencing the adverse event as masked (with only the initials of name and surname) in case the explicit consent of the said individual is not obtained. In such case, please ensure that the reporting – in secondary and tertiary reports – is made by a reporting individual who is disidentified yet who may ensure the follow-up and provide contact details thereof in order to enable our Company to follow up the adverse reaction in question.

In Terms of the Individuals Experiencing Adverse Events	
Personal Data Categories	Purposes for and Legal Basis of Processing of Personal Data
Identification Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) being expressly permitted by law, as stipulated in article 5(2)(a) of the LPPD; (ii) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(c) of the LPPD; (iii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iv) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes: Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; Conducting of Audit / Ethics Activities; Conducting of Activities in accordance with the Legislation; Follow-up and Conducting of Legal Affairs; Carrying out of Internal Audit / Investigation / Intelligence Activities; Conducting of Communication Activities; Conducting of Inspection of Business Activities; Protection of Public Health;

In Terms of the Individuals Experiencing Adverse Events	
Personal Data Categories	Purposes for and Legal Basis of Processing of Personal Data
	 Operation of Preventive Medicine; Conducting of Storage and Archiving Activities; Furnishing of Information to Authorized Individuals, Institutions and Organizations.
Contact Details Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) being expressly permitted by law, as stipulated in article 5(2)(a) of the LPPD; (ii) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(ç) of the LPPD; (iii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iv) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes: • Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; • Conducting of Audit / Ethics Activities; • Conducting of Activities in accordance with the Legislation; • Follow-up and Conducting of Legal Affairs; • Carrying out of Internal Audit / Investigation / Intelligence Activities; • Conducting of Communication Activities; • Conducting of Inspection of Business Activities; • Protection of Public Health; • Operation of Preventive Medicine; • Conducting of Storage and Archiving Activities; • Furnishing of Information to Authorized Individuals, Institutions and Organizations.
Visual and Audio Recording Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) being expressly permitted by law, as stipulated in article 5(2)(a) of the LPPD; (ii) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(c) of the LPPD; (iii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iv) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes:

In Terms of the Individuals Experiencing Adverse Events	
Personal Data Categories	Purposes for and Legal Basis of Processing of Personal Data
	 Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; Conducting of Audit / Ethics Activities; Conducting of Activities in accordance with the Legislation; Follow-up and Conducting of Legal Affairs; Carrying out of Internal Audit / Investigation / Intelligence Activities; Conducting of Communication Activities; Conducting / Inspection of Business Activities; Protection of Public Health; Operation of Preventive Medicine; Conducting of Storage and Archiving Activities; Furnishing of Information to Authorized Individuals, Institutions and Organizations.
Health Data	Your personal data, as limited with the criminal convictions and security measures, are processed within the scope of foreign trade process, on the basis of the personal data processing condition (legal ground) of being expressly permitted by law, as stipulated in article 6(3) of the LPPD, and for the following purposes: • Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; • Conducting of Audit / Ethics Activities; • Conducting of Activities in accordance with the Legislation; • Follow-up and Conducting of Legal Affairs; • Carrying out of Internal Audit / Investigation / Intelligence Activities; • Conducting / Inspection of Business Activities; • Protection of Public Health; • Operation of Preventive Medicine; • Conducting of Storage and Archiving Activities; • Furnishing of Information to Authorized Individuals, Institutions and Organizations.
Sexual Life Data	Your personal data, as limited with the criminal convictions and security measures, are processed within the scope of foreign trade process, on the basis of the personal data processing condition (legal ground) of being expressly permitted by law, as stipulated in article 6(3) of the LPPD, and for the following purposes: Conducting of Emergency Management Processes; Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; Conducting of Audit / Ethics Activities;

In Term	In Terms of the Individuals Experiencing Adverse Events	
Personal Data Categories	Purposes for and Legal Basis of Processing of Personal Data	
	 Conducting of Activities in accordance with the Legislation; Follow-up and Conducting of Legal Affairs; Carrying out of Internal Audit / Investigation / Intelligence Activities; Conducting / Inspection of Business Activities; Protection of Public Health; Operation of Preventive Medicine; Conducting of Storage and Archiving Activities; Follow-up of Requests / Complaints; Furnishing of Information to Authorized Individuals, Institutions and Organizations. 	
Processing/Transaction Security Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(c) of the LPPD; (ii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iii) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes: Conducting of Information Security Processes; Conducting of Audit / Ethics Activities; Conducting of Activities in accordance with the Legislation; Carrying out of Internal Audit / Investigation / Intelligence Activities; Conducting of Storage and Archiving Activities; Follow-up of Requests / Complaints; Ensuring the Security of the Data Controller's Operations; Furnishing of Information to Authorized Individuals, Institutions and Organizations.	
Request / Complaint / Suggestion Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(ç) of the LPPD; (ii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iii) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes:	

In Terms of the Individuals Experiencing Adverse Events	
Personal Data Categories	Purposes for and Legal Basis of Processing of Personal Data
Legal Action Data	 Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; Conducting of Information Security Processes; Conducting of Audit / Ethics Activities; Conducting of Activities in accordance with the Legislation; Carrying out of Internal Audit / Investigation / Intelligence Activities; Conducting of Communication Activities; Conducting of Inspection of Business Activities; Protection of Public Health; Operation of Preventive Medicine; Conducting of Storage and Archiving Activities; Follow-up of Requests / Complaints; Furnishing of Information to Authorized Individuals, Institutions and Organizations. Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(e) of the LPPD; (ii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iii) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes: Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; Conducting of Audit / Ethics Activities; Conducting of Audit / Ethics Activities; Conducting of Internal Audit / Investigation / Intelligence Activities; Conducting / Inspection of Business Activities; Conducting of Storage and Archiving Activities; Conducting of Storage and Archiving Activities; Follow-up of Requests / Complaints; Furnishing of Information to Authorized Individuals, Institutions and Organiz
Identification Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) being expressly permitted by law, as stipulated in article 5(2)(a) of the LPPD; (ii) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(ç) of the LPPD; (iii)

In Terms of the Individuals Experiencing Adverse Events	
Personal Data Categories	Purposes for and Legal Basis of Processing of Personal Data
	data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iv) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes:
	 Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; Conducting of Audit / Ethics Activities; Conducting of Activities in accordance with the Legislation;
	 Follow-up and Conducting of Legal Affairs; Carrying out of Internal Audit / Investigation / Intelligence Activities; Conducting of Communication Activities;
	 Conducting / Inspection of Business Activities; Protection of Public Health; Operation of Preventive Medicine;
	 Conducting of Storage and Archiving Activities; Furnishing of Information to Authorized Individuals, Institutions and Organizations.
Contact Details Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) being expressly permitted by law, as stipulated in article 5(2)(a) of the LPPD; (ii) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(c) of the LPPD; (iii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iv) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes:
	 Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; Conducting of Audit / Ethics Activities; Conducting of Activities in accordance with the Legislation;
	 Follow-up and Conducting of Legal Affairs; Carrying out of Internal Audit / Investigation / Intelligence Activities;
	 Conducting of Communication Activities; Conducting / Inspection of Business Activities; Protection of Public Health; Operation of Preventive Medicine;

In Terms of the Individuals Experiencing Adverse Events	
Personal Data Categories	Purposes for and Legal Basis of Processing of Personal Data
	 Conducting of Storage and Archiving Activities; Furnishing of Information to Authorized Individuals, Institutions and Organizations.
Visual and Audio Recording Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) being expressly permitted by law, as stipulated in article 5(2)(a) of the LPPD; (ii) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(ç) of the LPPD; (iii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iv) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes:
	 Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; Conducting of Audit / Ethics Activities; Conducting of Activities in accordance with the Legislation; Follow-up and Conducting of Legal Affairs; Carrying out of Internal Audit / Investigation / Intelligence Activities; Conducting of Communication Activities; Conducting / Inspection of Business Activities; Protection of Public Health; Operation of Preventive Medicine; Conducting of Storage and Archiving Activities; Furnishing of Information to Authorized Individuals, Institutions and Organizations.
Processing/Transaction Security Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(ç) of the LPPD; (ii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iii) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes: • Conducting of Information Security Processes; • Conducting of Audit / Ethics Activities;

In Terms of the Individuals Experiencing Adverse Events	
Personal Data Categories	Purposes for and Legal Basis of Processing of Personal Data
	 Carrying out of Internal Audit / Investigation / Intelligence Activities; Conducting of Storage and Archiving Activities; Follow-up of Requests / Complaints; Ensuring the Security of the Data Controller's Operations; Furnishing of Information to Authorized Individuals, Institutions and Organizations.
Request / Complaint / Suggestion Data	Your personal data within this category are processed on the basis of the personal data processing conditions (legal grounds) of (i) data processing being required for the data controller's compliance with a legal obligation, as stipulated in article 5(2)(c) of the LPPD; (ii) data processing being required for the establishment, exercise or protection of a right, as stipulated in article 5(2)(e) of the LPPD; and (iii) data processing being required for the legitimate interests of the data controller, provided not to impair the fundamental rights and freedoms of the data subject, as stipulated in article 5(2)(f) of the LPPD, and for the following purposes: • Attainment / Monitoring / Evaluation / Reporting of Adverse Reactions; • Conducting of Information Security Processes; • Conducting of Activities in accordance with the Legislation; • Carrying out of Internal Audit / Investigation / Intelligence Activities; • Conducting of Communication Activities; • Conducting of Inspection of Business Activities; • Protection of Public Health; • Operation of Preventive Medicine; • Conducting of Storage and Archiving Activities; • Follow-up of Requests / Complaints; • Furnishing of Information to Authorized Individuals, Institutions and Organizations.

1. The Domestic and Cross-Border Transfer of Your Personal Data to Third Parties

Your personal data which are retained by our Company may be accessed solely by our personnel who have been granted with restricted access authorization for the aforementioned purposes and who are under the (professional) duty of secrecy, to the extent as is necessary to fulfill their duties, and will not be transferred to third parties located in Turkey and/or abroad in cases where the conditions for transfer which are regulated in articles 8 and/or 9 of the LPPD are not satisfied. Nevertheless, your personal data which are processed within the scope of each personal data category listed hereinabove may be transferred to the following recipient groups if the aforesaid personal data processing conditions (legal

grounds) for the data category concerned are further satisfied in terms of the purposes for transfer, and in accordance with articles 8 and/or 9 of the LPPD:

- to the *authorized public institutions and organizations*¹ (e.g. Turkish Medicines and Medical Devices Agency, Ministry of Health, World Health Organization²) in Turkey and/or abroad, as limited with the identification, contact, legal action, transaction security, visual and audio and request / complaint / suggestion personal data categories, for the purposes as specified hereinabove for each data category, and particularly, in order to fulfill our Company's statutory obligations under the legislation concerning the monitoring of safety of pharmaceutical products;
- to our *group companies including our Company's affiliates* and *our contract manufacturing business partners* located in Turkey and/or abroad, as limited with the identification, contact, legal action, transaction security, visual and audio and request / complaint /suggestion personal data categories, for the purposes as specified hereinabove for each data category, and particularly, in order to facilitate the processing to the global pharmacovigilance data base if so required, and the compliance with the policies and procedures of our group companies; and
- to our *suppliers* (e.g. Ministry of Health accredited companies from which pharmacovigilance service support is received, information technology, marketing authorization (regulatory affairs), legal, compliance) located in Turkey and/or abroad, as limited with the identification, contact, legal action, transaction security, visual and audio and request / complaint / suggestion personal data categories, for the purposes as specified hereinabove for each data category, and particularly, in order to ensure the conducting of the pharmacovigilance processes.

2. The Period for Processing of Your Personal Data

Your personal data which are acquired during our Company's operations are retained and destroyed pursuant to the general principles and regulations laid down in our Company's policies and procedures on retention and destruction, which are drafted in accordance with primarily, the Constitution, and the LPDD, the Regulation on the Deletion, Destruction and Anonymization of Personal Data and other applicable legislation.

Within this scope, if all of the aforementioned personal data processing conditions cease to exist, your personal data will be destructed accordingly. Given that your personal data which are processed by our Company within the scope of pharmacovigilance activities (e.g. adverse reaction / special situation reports) are vital for public health, they must be retained during the period in which the marketing authorization of the pharmaceutical product is in force and from the effective date of cancellation or transfer of the marketing authorization until the expiry of the statutory limitation period (currently, 10 years).

3. Your Rights under the LPPD

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¹ Our Company may be required to further report your personal data which are acquired during the pharmacovigilance process conducted in this regard and which are listed in the personal data categories above, to overseas partners, institutions such as the World Health Organization, including the countries with varying levels of data protection. Nevertheless, your personal data which are included in the said reports will be processed in accordance with the data minimization principle and if possible, the measure of data pseudonymization.

<u>Individual Experiences the Adverse Event (Affected Individual):</u> Information such as age or date/year of birth, gender, initials of the name-surname of the patient (full patient name will never be provided) will be sought. <u>Individual Reporting the Adverse Reaction (Reporting Individual):</u> Information such as name-surname, professional work experience, initials of name and surname, e-mail address, phone number of the reporting individual in order to allow the institution to follow up the adverse reaction incident will be sought.

² Currently, the data may be transferred to the database of the World Health Organization as anonymized or pseudonymized, pursuant to the Drug Monitoring and Cooperation Program.

Pursuant to article 11 of the LPPD, you possess the following rights, as a data subject:

- being informed of whether your personal data are processed by our Company or not;
- requesting information thereon if your personal data have been processed;
- being informed of the purpose for the processing of your personal data and whether such data were used in conformity with such purpose or not;
- knowing the third parties in Turkey or abroad to whom/which personal data are transferred;
- requesting the rectification of incomplete or inaccurate personal data which were processed and the notification, of the operation carried out within this scope, to third parties to whom/which personal data were transferred;
- requesting the deletion or destruction of personal data despite the processing in accordance
 with the law and other applicable legal provisions, once the reasons necessitating the
 processing cease to exist, and within this scope, if the personal data were processed
 incompletely and inaccurately, the notification, of the operation carried out within this scope,
 to third parties to whom/which personal data were transferred;
- objecting to any outcomes to your detriment by means of the analysis of the processed data exclusively through automated means;
- claiming the compensation of your damages, in case you incur any damages due to the unlawful processing of personal data.

You may submit your application regarding your aforementioned rights, in accordance with the provisions of the Communiqué on the Procedures and Principles of Application to the Data Controller (in writing or electronically, via registered electronic mail (KEP) address, signed with secure electronic signature or mobile signature, or via your e-mail address which had previously been notified to our Company and which is recorded in our system - along with the information / documentation* verifying your identity in order to enable our Company to confirm your status as an actual rightholder/beneficiary (e.g. Turkish ID number or passport number for citizens of other countries, residential address / workplace address for notification/service, mobile phone / landline /facsimile number, e-mail address) through the channels which are indicated in the applicable legislation, in accordance with the procedures and principles which are laid down in the applicable legislation, particularly via the e-mail address of KVKKIRTIBAT@bilimilac.com. Your application will be concluded free of charge as soon as possible and within 30 (thirty) days at the latest, depending on the nature of your request; however, in case the transaction requires an additional cost, you may be charged according to the tariff determined by the Personal Data Protection Board.

* Please note that <u>no special categories of personal data (e.g. religion or blood type information)</u> should be included in the said documentation.