Data processing for the purposes of medical science – reception and investigation of adverse reactions/adverse events/incidents/special situations related to medicines, cosmetics, medical devices operation of a scientific information service, involvement in market research, monitoring of websites and social media platforms operated by Egis.

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
1. Receiving, evaluating, following up as necessary, storing and, where appropriate, reporting to the European Medicines Agency (EMA)/national authorities and/or to contractual partners, any pharmacovigilance adverse events/adverse reactions and special situations related to medicinal products.	Fulfilment of the legal obligations applicable to Egis under Article 6 (1) c) of GDPR. Provision of law prescribing the legal obligation: Section 6 (2) of Decree 15/2012 (VIII. 22.) of the Ministry of Human Resources on the pharmacovigilance of medicinal products for human use. Article 6 of the aforementioned regulation lays down Egis' obligation to record, report and transmit suspected adverse reactions. Available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129132.pdf	Data provided by the data provider in the report. Typically: name, age, gender, name of medicinal product used, illness, treatments applied, laboratory results, test results, complaints. If the data provider is not the patient, the name and contact details of the data provider as well as the reported data, especially the name, contact details, age, gender, data concerning medicines taken, illness of the patient treated by him/her, treatments applied, laboratory results, test results, complaints are also processed by Egis. Follow-up may be necessary to investigate the notification (e.g., in the case of an unidentified person making the report, a	**10 years** from the expiry of the marketing authorisation of the product (in accordance with Module I of the Guideline on good pharmacovigilance Practices [GVP] of EMA – European Medicines Agency). **Persons who have access within Egis:** **1.** Staff of the Drug Safety Department, Trade Center; **2.** Clinical Pharmacology and Development Division including the Staff of the Clinical Expert and Product Information Editor Department; **3.** Staff of the Quality Management Directorate; **4.** Staff of the Product information Service; **5.** Where appropriate, the competent in-house legal

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	For the follow-up obligation of Egis see Section VI.B.3 of the GVP VI Module under the following title: "Follow-up of reports". **Module VI of GVP is available at** https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf **In respect of health data:** Article 9 (2) h) of the GDPR – processing is necessary for the purposes of preventive medicine, the provision of healthcare or treatment on the basis of Union or Member State law or pursuant to contract with a healthcare professional; or Article 9 (2) i) of the GDPR –	patient, or exposure to a medicine during pregnancy or breastfeeding), which can be done through the contact details provided in the notification by the person submitting the notification, or through the contact details at his choice (written form is preferred for verifiability of follow-up). Egis shall make two attempts to contact the person submitting the notification. Fulfilment/rejection/ignoring the request is voluntary. Paper based data shall be kept by Egis in fire-, water-, burglary- and rodent-proof premises equipped with an alarm, complying with the provisions of Module I of Guideline on Good Pharmacovigilance Practices (GVP).	counsel or the communications staff member may become familiar with the content of the report. **ARIS Global** (www.arisglobal.hu; registered seat: ArisGlobal LLC: Ponce De Leon Blvd Coral Gables, FL, USA, 33134; adrianno@arisglobal.com) provides hosting services only in the territory of the EU as a data processor. Subsidiaries and trade representative offices of Egis may also forward reports on adverse reactions to Egis as marketing authorisation holder. Contact details of subsidiaries and trade representative offices: https://hu.egis.health/#/map The Egis subsidiaries act according to Egis' instructions (they qualify as data processors),

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	processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy.		receiving local notifications, monitoring legislation and performing translation tasks, which are regulated by an operational level instruction. Egis may transfer the data to its contracting partners if it is required to do so by contract (e.g., if the partner is subject to pharmacovigilance obligation) – in this case Egis shall arrange for the masking (anonymisation) of the data. Egis may also transfer data upon the request of authorities, but only in anonymized form. In the case of an inspection (official audit or partner audit, which is intended to verify compliance with the rules governing the manufacture of medicinal products), the authority or the contractual partner of Egis may also inspect

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			the data.
2. Receiving, evaluating, following up as necessary, storing and reporting, as necessary, any adverse events (hereinafter referred to as cosmetovigilance) of cosmetic products to national authorities and/or contractual partners.	Fulfilment of the legal obligations applicable to Egis under Article 6 (1) c) of GDPR. Provision of law prescribing the legal obligation: Regulation 1223/2009/EC of the European Parliament and of the Council of 30 November 2009 on cosmetic products provides that in the event of a serious adverse reaction, the responsible person and distributors shall notify the competent authority of the Member State where the reaction occurred (see Article 23). Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AL%3A2009%3A342%3A0059%3A0209%3AEN%3APDF	See Section 1.	**Data retention period: 10 years from the date when the last cosmetic product was put on the market.** (See: Article 11 of Regulation 1223/2009/EC). **Persons who have access within Egis:** See Section 1. Additional persons with access rights are those specified in Section 1, with the exception of ARIS Global data processor.

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	Expectations related to Article 23 (for the **maintenance of the system**) are formulated in point 3.9 of the Annex to the Commission Implementing Decision "*on guidelines for Annex I to Regulation 1223/2009/EC of the European Parliament and of the Council on cosmetic products*" (25 November 2013). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D0674&from=EN For more information on the **follow-up** see page 5 (section 2.4.1) of the following guideline (SUE REPORTING GUIDELINES): https://ec.europa.eu/docsroom/documents/34783 The processing of health records		

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
	shall be governed by the conditions under Article 9 of GDPR, referred to in Section 1.		
3. Receiving, evaluating, following up as necessary, storing and reporting, as necessary, any medical device incidents (medical device vigilance) to national authorities and/or contractual partners.	Fulfilment of the legal obligations applicable to Egis under Article 6 (1) c) of GDPR. Provision of law prescribing the legal obligation: the provisions of Section 21 of Decree 4/2009 (III.17.) of the Ministry of Health on medical devices, of Regulation 2017/745/EU of 5 April 2017 on medical devices, amending Directive 2001/83/EC and Regulation 178/2002/EC, Regulation 1223/2009/EC and repealing Council Directives 90/385/EEC and 93/42/EEC, hereinafter referred to as "**MDR**": The **development of an appropriate vigilance system** is prescribed by Article 10 (13) of the MDR, the establishment of a post-market surveillance system by Article 83 (2) and the	See Section 1.	**Data retention period:** 10 years after the last device was put on the market, 15 years for implantable devices (See also point 7 of Chapter III of Annex IX to MDR). **Persons who have access within Egis:** See Section 1. Additional persons with access rights are those specified in Section 1, with the exception of ARIS Global data processor. CATSWEB (http://tgyqmsappprod01.egis.hu/catswebnet/) is a system operated by Egis.

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	reporting of adverse events involving medical devices by Articles 87 and 88. The **follow-up obligation** of Egis is set out in Article 87 (11) of Chapter VII of MDR. MDR is available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN For Decree 4/2009 (III. 17) of the Ministry of Health see: https://net.jogtar.hu/jogszabaly?docid=a0900004.eum The processing of health records shall be governed by the conditions under Article 9 of GDPR, referred to in Section 1.		

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4. Evaluating and storing vigilance trainings and training-related tests provided to Egis' contractual partners and persons acting on behalf of its subsidiaries, receiving the notifications set out in points 1–3 of hereof.	Fulfilment of the legal obligations applicable to Egis under Article 6 (1) c) of GDPR. Provision of law prescribing the legal obligation: Requirements related to proper education are also set out in the Guideline on good pharmacovigilance practices (GVP) Module I (I.B.7). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129132.pdf	Scope of processed data: e-mail address, signed declarations (of having mastered the procedure complying with the training provided by Egis), test results. Egis stores these data on paper and also in electronic form on the central encrypted drive.	**Data retention period:** 5 years after the end of the lifetime of the vigilance system (see: GVP Module I, point I.C.2.4, 5th indent). **Persons who have access within Egis:** **1.** Staff of the Drug Safety Department, Trade Center; **2.** Staff of the HR Directorate. Egis may transfer the data to its contracting partners if it is required to do so by the contract (e.g., if the partner is subject to vigilance obligation) – in this case Egis shall arrange for the masking (anonymisation) of the data. Egis may also transfer data upon the request of authorities, but only in anonymised form. In the case of an inspection (official audit or partner audit, which is intended to verify compliance with the rules

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			governing the manufacture of medicinal products), the authority or the contractual partner of Egis may also inspect the data.
5. Operating a scientific information service where anyone (especially physicians, patients) can inquire about Egis products. In the inquiry it is not necessary to provide any data that would allow identification; however, Egis can only investigate adverse reaction reports if you provide identification data. If an adverse reaction is also reported when medical information is requested, then Egis will handle this in accordance with the rules on reporting adverse reactions,	Fulfilment of the legal obligations applicable to Egis under Article 6 (1) c) of GDPR. Provision of law prescribing the legal obligation: performing the **obligation to set up and operate a service** under Recital (40) and Article 98 of Directive 2001/83/EC on the community code relating to medicinal products for human use. Article 9 (2) i) of the GDPR – processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or	Data provided in the inquiry, report, especially: Inquirer/notifier's name, contact details, contact with the patient. Patient's name, occupation, name of the medicinal product, question the patient asks, contact details.	**Data retention period: 3 years** after the calendar year of the response for the purpose of auditing requests for information (e.g., in case of a possible audit), after 3 years personal data will be anonymized for statistic purpose. E-mails arrive to Egis central mailbox (mailbox@egis.hu), resp. help@egis.hu mailbox which connects to this purpose will be transferred to the relevant department (see below) for further administration/ investigation and will be deleted in 30 days afterwards from this mailbox. The relevant department will be responsible for storing the data for

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based on the relevant section of this Notice (depending on whether the notification concerns a medicinal product, a cosmetic product or a medical device).	ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy.		3 year (and deleting) . **Persons who have access within Egis:** **1.** Clinical Pharmacology and Development Division including the Staff of the Clinical Expert and Product Information Editor Department. **2.** Staff of the Product Information Service. **3.** If the report is also a report on adverse reaction/safety relevant information, it will be transferred to the Drug Safety Department. See Section 1. **4.** If the application contains a quality complaint, it will be transferred to the Quality Management Directorate. **5.** Where appropriate, the competent in-house legal counsel or the communications staff member may become familiar with the content of the report.

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			In the case of an inspection (official audit or partner audit which is intended to verify compliance with the rules governing the manufacture of medicinal products), the authority or the contractual partner of Egis may inspect the data.
6. Handling of messages received on the Egis Scientific Information Service's answering machine. Egis takes direct telephone calls from 8 am to 5 pm Monday to Friday. Calls made after this time or on weekends (i.e., outside working hours) will be recorded on Egis voicemail and listened to on the next working day.	Article 6 (1) a) of GDPR – the data subject's consent, which is given by the data subject when he makes a notification after he has been provided with information on data processing over the phone. The data subject may choose other forms of communication (e.g., send an e-mail to help@egis.hu or a letter to the registered office of Egis), or contact Egis by telephone during working hours (in this case, the answering machine is not activated and no recording is made).	Voice of the data subject, the information, questions, data shared by him or her, in particular his/her name, contact details, the name of the product used. A memo will be taken of the notifications made.	**Data retention period**: The form completed on the vigilance notification will be retained for the retention period set out in the relevant section of this notice, while the audio recording will be deleted within 15 days after drawing up the form. **Persons who have access within Egis**: The answering machine will be listened to by the staff of the Security Division and they will forward the form to the organisational unit authorised to investigate the respective case. For the list of these

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
	The data subject may withdraw his or her consent at any time. The withdrawal of consent will not affect the lawfulness of data processing based on consent and performed prior to the withdrawal. Please note that if Egis is under a legal obligation to investigate the notification as set out in the purposes above, it will destroy the recording at your request, but it is obliged to carry out the assessment, investigation, notification and transmission based on the notification, and your withdrawal shall not apply to this.		organisational units see Section 1–3. **Future Security Zrt.** (H-1148 Budapest, Fogarasi út 5.) supports Egis as a data processor. The persons involved participate in vigilance training.
7. Data processing related to the involvement and participation in Egis sponsored market research related to the use of Egis products, the habits and attitudes of patients and doctors.	Article 6 (1) a) of the GDPR, the data subject's voluntary consent and, with regard to any health data that may be shared, the data subject's explicit consent in accordance with Article 9 (2) a) of the GDPR.	Scope of processed data: name, contact details (usually e-mail address, phone number), signed declaration (to participate in market research), data shared during the market research, information that can be linked to the data subject, possible health	**Data retention period:** If the case set out in points 1 to 3 is reported in the course of the market research, the data retention period for the report will be as set out in the relevant section of this notice. See also point 4 of this notice for

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For the clinical and NIT trials see the relevant data processing notice of Egis.	The data subject may withdraw his or her consent at any time. The withdrawal of consent will not affect the lawfulness of data processing based on consent and performed prior to the withdrawal. In the absence of consent, we are not in the position to involve you in the market research.	data, medical history, experience shared. If the market research is conducted in the online space: in addition to the above, also photo and voice. In the case of recording, the content of the recording. During the market research, the data subject can refuse to answer any question and is free to choose what to share. The information shared by the data subject will be recorded by Egis' external partner in an anonymous summary and Egis will receive this.	the training of persons conducting market research. For documentation other than these, the data retention period set out in the Egis data processing notice entitled "Data processing related to contractual partners" shall apply (5 years from the termination of the contractual relationship (Section 6:22 (1) of the Civil Code. **Persons who have access within Egis**: For notifications involving vigilance, see the relevant section of this notice. The relevant department of Egis responsible for conducting the market research has access to the documentation not related to vigilance. At Egis' discretion it may participate in interviews (including online) or inspect recordings made by an external

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			partner (but it will not record any data). Egis usually carries out market research with an external partner, and the data subject is always informed of the partner. These partners act as data processors.
8. Monitoring, recording and, if necessary, follow-up of the notifications received on the websites and social media platforms (Facebook, Instagram, Youtube and LinkedIn) operated and maintained by Egis in accordance with points 1–3 hereof**.** Egis will place a notice on the sites subject to monitoring, informing the data subjects how and where they can submit a notification. For the investigation of notifications see Section 1, 2 and 3 hereof.	Fulfilment of the legal obligations applicable to Egis under Article 6 (1) c) of GDPR. Provision of law prescribing the legal obligation: Regarding the control of the internet and digital interfaces, such as social networks and websites, for the obligations of Egis see GVP, Module VI, point VI.B.1.1.4, under the following title: "*Information on suspected adverse reactions from the internet or digital media.*" **Available at:** https://www.ema.europa.eu/en/d	**Scope of processed data:** provided personal data; typically: name (username), email address, age, name of medicinal product used, illness, complaints; if the data provider is not the patient, the name and contact details of that person as well as the data provided by him/her are also processed by Egis. Entries, comments and messages containing vigilance content will be recorded and logged in the form of a print screen by the competent employee of Egis and stored electronically on Egis' central encrypted drive (with limited access).	**Data retention period:** it shall be governed by the data retention period applicable to the product type stipulated herein. **Persons who have access within Egis**: Monitoring and follow-up, if necessary, is carried out by a competent employee dedicated to this task (the rules of appointment are regulated by internal instructions) or by an external contracted partner commissioned by Egis, acting as Egis' data processor. The list of these partners may change continuously. The list may be obtained any time by writing to

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	ocuments/regulatory–procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf Additional background information: CIOMS 2001. Report of CIOMS Working Group V. – Current Challenges in Pharmacovigilance: Pragmatic Approaches – II. SOURCES OF INDIVIDUAL CASE REPORTS, point d), provisions under the heading "The Internet". Available at: https://cioms.ch/wp-content/uploads/2017/01/Group5_Pharmacovigilance.pdf		help@egis.hu. Once the notification has been registered, the relevant section of this notice specifies the persons with access rights.