4.8 Processing of personal data related to customer and quality complaints

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
1. Processing customer complaints (medicinal products and medical devices)	**For medicines:** Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products, Section 4(8)(b) to (d) and Section 17, as well as the investigation, recording and notification obligations under Decree 44/2005 of 19 October 2005 of the Minister of Health on the Personal and Material Conditions of the Manufacture of Medicines for Human Use, Annex 1 / Complaints, withdrawal from circulation and emergency unblinding. In addition, relevant regulations are given in the Good Manufacturing Practice (GMP) containing correct pharmaceutical practices relevant to Egis. In accordance with the above, for medicinal products, the manufacturer (i.e. Egis) creates a system suitable for recording and investigating complaints as well as an efficient system for immediately withdrawing medicinal products from circulation. The manufacturer records and investigates all	Data voluntarily given by the submitter of the complaint. The submitter is usually a pharmacist, wholesaler, Egis subsidiary or representative office, or contractual partner, and rarely directly the patient. In order to handle the complaint, Egis requests the name and manufacturer's serial number of the product, and a description of the problem in every case. In the course of submitting and handling the complaint, Egis may learn the name, address, telephone number, e-mail address and illness of the patient, the names of the medicines taken by the patient, information related to the patient's health, treatments used, laboratory results, examination results as well as information related to the patient's lifestyle. If the submitter of the complaint is not the patient, in addition to the above data, Egis also processes the	Documents and correspondence related to customer complaints and to medicine withdrawals related to customer complaints are classified 'not for disposal' in view of the fact that, under the GMP regulations relevant to Egis, such documents related to a given product must be retained for the entire life-cycle of the product (i.e. while the given product is in circulation). These documents are archived using CATSWeb's CMP system (the electronic system used by Egis). Personal data will be deleted after **1 year** from the closure of the complaint. Thereafter, Egis will only retain data in an anonymised form that cannot be connected with data subjects in relation to the complaint. **Persons entitled to access data at Egis**: typically, designated employees at the Quality Management Directorate (employee receiving complaints, recording complaints and central manager of the complaints), who will transmit letters and related data

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	complaints with regard to any defects. **For medical devices**: Decree 4/2009 of 17 March 2009 of the Minister of Health on Medical Devices, Section 21/A (7). Under the Decree, the manufacturer or authorised representative is obliged to record all events related to the device and implement changes necessary for the safe use of the device. The submitter of the complaint provides the contents of the complaint and the personal data included in it voluntarily but Egis – irrespective of the potential withdrawal of the complaint – is obliged to process these in order to comply with the legal obligations it is subject to (GDPR Article 6(1)(c)).	name and contact details of the person making the complaint.	only on an anonymised method that does not enable the identification of data subjects (letters are attached without the transmission of the sender's personal data). Data recorded in the Catsweb system are accessed with read-only rights by the Catsweb users specified by the Quality Management Director. The period of access by employees authorised to access personal data can also be set in the system. Catsweb system operator: **CNW Zrt.** Seat: 1181 Budapest, Wlassics Gy. u. 50. Telephone: +36 1 323 2600 Fax: +36 1 303 0880 E-mail: office@cnw.hu Web: www.cnw.hu Egis may disclose the data in response to an official request, but, unless obliged by the authority, only in an anonymised form.
2. Management of the claims pertaining to the products distributed by Egis (e.g.	Article 6 (1) f) of the GDPR – the data processing is necessary for the	Personal data (the identification and contact data of the individuals, including the legal representative).	Until the end of the limitation period of the claims regarding the products distributed by Egis

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complaints, claims for damages) and processing and transferring the personal data and the related health data to the supplier of the given product, in order to inform such supplier of the relevant claim, and involve the supplier into the claim management, if necessary. For example: the supplier and/or the manufacturer may participate in the investigation of the claim and finding a solution, including the compensation and indemnity for defective / inadequate quality of delivered products.	legitimate interests of Egis and the supplier and/or the manufacturer. The legitimate interest: handling the compliance questions regarding the supply agreement and/or the technical (quality) agreement for the given product, in addition, establishing, exercising and defending legal claims regarding the product and the supply agreement and/or the technical (quality) agreement. rticle 9 (2) f) of the GDPR – the data processing is necessary for the establishment, exercise or defense of legal claims; Article 9 (2) i) of the GDPR – the data processing is necessary for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of medical products in accordance with the applicable laws.	Health data (medical documentation of the individual).	Pharmaceuticals PLC, or until the closing of the dispute resolution procedure regarding the claim. **Persons entitled to access data at Egis:** typically, designated employees at the Quality Management Directorate (employee receiving complaints, recording complaints and central manager of the complaints), who will transmit letters and related data only on an anonymised method that does not enable the identification of data subjects (letters are attached without the transmission of the sender's personal data). Egis may disclose the data in response to an official request, but, unless obliged by the authority, only in an anonymised form.