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<b>1 Register controller</b>	<p><b>Name</b> The Social Insurance Institution of Finland (Kela)</p> <hr/> <table border="0"> <tr> <td><b>Postal address</b></td> <td><b>Postal code</b></td> <td><b>Phone number</b></td> </tr> <tr> <td>PO Box 450</td> <td>00056</td> <td>020 634 11</td> </tr> </table> <hr/> <p><b>Offices</b> Nordenskiöldinkatu 12, 00250 Helsinki</p>	<b>Postal address</b>	<b>Postal code</b>	<b>Phone number</b>	PO Box 450	00056	020 634 11
<b>Postal address</b>	<b>Postal code</b>	<b>Phone number</b>					
PO Box 450	00056	020 634 11					
<b>2 Person responsible for register-related issues or contact person</b>	<p><b>Name</b> Kanta services asiakaspalvelu@kanta.fi</p>						
<b>3 Name of register</b>	<p>Reseptikeskus (Prescription Centre)</p>						
<b>4 Purpose of processing of personal data / purpose of use of the register</b>	<p>Under section 18 of the Act on Electronic Prescriptions (61/2007) the Social Insurance Institution of Finland (hereinafter referred to as Kela) is the register controller for the Prescription Centre. Kela is responsible for ensuring the usability and consistency of the data stored in the Prescription Centre, for the integrity of the data contents, and for the storage and destruction of the data.</p> <p>In implementing the processing of personal data, Kela adheres to the EU General Data Protection Regulation, other laws governing the processing of personal data and the Act on Electronic Prescriptions.</p> <p>The purpose of the register is to enable the storage and preservation of electronic prescriptions under the Act on Electronic Prescriptions and related dispensing data and requests for renewal in the centralised nationwide Prescription Centre. Electronic prescriptions stored in the Prescription Centre may be dispensed in accordance with consent given in My Kanta from any pharmacy that has joined the electronic prescription system and from such pharmacies in Member States of the European Union as referred to in section 23 a of the Act on Electronic Prescriptions.</p> <p>Electronic prescriptions and related dispensing data stored in the Prescription Centre can, on grounds laid down in the Act on Electronic Prescriptions, be used e.g. when checking a patient's overall medication, in official supervision of social and health care providers and pharmacies, when determining benefits under the Health Insurance Act and in scientific research, reporting and statistics. .</p> <p>Patients are entitled to receive a prescription on paper or by phone instead of electronically in the event of technical problems, exceptional events or comparable situations.</p> <p>Electronic prescriptions stored in the Prescription Centre are available to social and health care providers and to pharmacies for 30 months. They are stored for a further 20 years and thereafter destroyed. Prescription data may be viewed via the My Kanta service.</p>						
<b>5 Information content of the register</b>	<p>The Prescription Centre contains electronic prescriptions under the Act on Electronic Prescriptions, related dispensing details and requests for renewal.</p>						

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	<p>Appendix 1 at the end of this statement contains data and groups of data contained in the register.</p>
<p><b>6 Regular sources of data</b></p>	<p>An electronic prescription can be issued by a doctor, dentist, medical or dental student with authorisation to prescribe medicines, or nurse whose right to prescribe medicines has been verified.</p> <p>The pharmacy must store prescriptions received on paper or by phone and related dispensing data in the Prescription Centre if the prescription has been issued in writing or by phone for example because of technical problems.</p> <p>Notes on the prescription regarding the dispensation are made and stored at the pharmacy by a chief pharmacist, pharmacist or health care professional authorised to dispense medicines.</p>
<p><b>7 Regular disclosure of data and transfer of data outside the EU or the EEA</b></p>	<p>Appendix 2 at the end of the statement contains information on situations when it is possible to disclose prescription and dispensing data under the Act on Electronic Prescriptions and other legislation, grounds for the disclosure of data and the mode of data disclosure.</p> <p>Data are not transferred outside the EU or the EEA.</p>
<p><b>8 Principles of register security</b></p>	<p>The data stored in the Prescription Centre are confidential data on a person's state of health.</p> <p><b>Organizational measures</b></p> <p>Social and health care providers, pharmacies, independent professionals and Kela must, for their part, follow and monitor the legality of the data processing, and each party must have a self-monitoring plan to ensure data security and data protection. Kela, the social or health care provider and the pharmacy must have an appointed privacy officer for follow-up and supervisory duties.</p> <p>Kela, the responsible manager of the social or health care provider and the owner of the pharmacy shall issue written instructions on the processing of data in the Prescription Centre and ensure sufficient competence and know-how among the personnel when processing a patient's data.</p> <p>Kela, social or health care provider and pharmacy must on their own initiative take necessary measures if data stored in the Prescription Centre have been unlawfully accessed, used or disclosed.</p> <p>For follow-up and monitoring purposes, social and health care providers that have joined the electronic prescription system and the pharmacy are entitled to receive log information from Kela, insofar as the personnel of the provider or pharmacy have accessed and processed data in the Prescription Centre.</p> <p>Pharmacies in other member states of the European Union interact with the Prescription Centre through contact points in the member state in question or through national Finnish contact points. Contact points of other member states</p>

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are entitled to receive log information from Kela to the extent that such information is needed to correct problems or issue official statements.

**Technical protection**

The viewing, storing and other processing of data in the Prescription Centre requires individualised strong authentication of the handler and administration of access rights related to the system.

The Population Register Centre is responsible for the authentication and certification services as regards electronic prescriptions. The European Commission is responsible for certification services in relation to national contact points.

For their part, the social or health care provider, pharmacy and Kela are responsible for the administration of user rights.

Log information is stored in the log of the prescription centre every time data in the Prescription Centre are viewed or processed.

**Physical protection of environment and devices**

The data stored in the Prescription Centre are technically protected from change and deletion.

The facilities of Kela and the data are physically located in Finland. Limited access to the facilities is provided to Kela technical maintenance personnel insofar as their job duties so require.

**9 Right of access**

Patients have the right to check what information is stored about them in the Prescription Centre. A request to check information can be made on an official Kela form available from social and health care providers that have joined the electronic prescription system, from pharmacies, and from Kela offices. Requests to check the information stored in the Prescription Centre should be addressed to Kela (Registry, PO Box 450, 00056 Kela). Requests can be made by contacting Kela's Registry by phone or by email ([kirjaamo@kela.fi](mailto:kirjaamo@kela.fi)). A reply to the request is as a general rule provided free of charge.

**10 Right to request the correction of data**

Patients have the right to request that erroneous data stored in the Prescription Centre is corrected. If a patient or his/her legal representative requests the correction of an error caused by information provided by a prescriber or dispenser of a medication, the request for correction must be directed to the prescriber or dispenser or to the organisation that employed them at the time.

In other situations or if the request concerns dispensing data recorded by a pharmacy in another European country, the request to correct the data is sent in writing to Kela (Registry, PO Box 450, 00056 Kela). If it is not possible to comply with the request, Kela provides the patient with a certificate of denial. The certificate of denial states the reasons why the patient's or the patient's legal representative's request has not been accepted. After having received the

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	<p>certificate of denial, the patient can bring the matter to the attention the competent supervisory authority.</p>
<p><b>11 Right to file a complaint with a supervisory authority</b></p>	<p>If a patient considers that his or her personal data is processed in a way which contravenes the applicable provisions on data protection (Articles 12–22 of the EU General Data Protection Regulation), the patient may file a complaint with the competent supervisory authority. In Finland, that competent supervisory authority is the Data Protection Ombudsman.</p>
<p><b>12 Other rights related to the processing of personal data</b></p>	<p>Patients can use the My Kanta service to view the data stored in the Prescription Centre and check to which social and health care providers and pharmacies the data have been disclosed.</p> <p>Patients are entitled to file a request with Kela to obtain log information in order to find out which persons who have processed and accessed the data stored on them in the Prescription Centre.</p> <p>The request to obtain log information should be made on an official Kela form available from social and health care providers that have joined the electronic prescription system, from pharmacies and from Kela offices. The request is addressed to Kela (Registry, PO Box 450, 00056 Kela). Requests can be made by contacting Kela’s Registry by phone or by email (<a href="mailto:kirjaamo@kela.fi">kirjaamo@kela.fi</a>). A reply to the request is as a general rule provided free of charge.</p> <p>Log information that is more than two years old cannot be examined, unless there are justifiable reasons for this. The patient must not use or disclose the log information he or she has obtained for other purposes.</p> <p>If the patient on the basis of the log information considers that his or her has been processed without justification, he or she can request a statement from the relevant pharmacy or social or health care provider. If the pharmacy is in another European country, the request is made to Kela.</p> <p>The patient has the right to obtain the data again if there is a justifiable reason for this in order to secure the patient's privileges and rights. If data are disclosed again, Kela can request a fee that corresponds to the cost of disclosing the data.</p> <p>The Prescription Centre is a service based on law (Act on Electronic Prescriptions) implemented and maintained by Kela. Kela’s operations are based on national laws. Therefore, the right under Article 17 of the EU General Data Protection Regulation of data subjects to obtain the erasure of personal data and the right under Article 20 to transmit data from one controller to another are not applied to data stored in the Prescription Centre.</p>

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## Appendix 1

### The prescription centre contains the following data and groups of data:

#### Prescription data

- Patient data
- Data on the prescriber
- Organisation data
- Data on the writing of the prescription
- Data on the medicine and the packaging
- Other prescription data

#### Data on medicine dispensation

- Patient data
- Data on the compilation of the medicine dispensation
- Data on the medicine and the packaging on dispensation
- Other medicine dispensation data

#### Data on cancellation of the prescription

- Data content of the prescription
- Data on cancellation of the prescription

#### Data on correction of the prescription

- Data content of the prescription
- Data on the correction of the prescription and on the person making the correction

#### Data on blocking of prescription and cancellation of the blocking

- Details on blocking
- Details on cancellation of blocking
- Other necessary data concerning the blocking and the cancellation of the blocking

#### Data on reservation of prescription and cancellation of the reservation

- Date of reservation
- Reason for reservation (optional)

#### Data on cancellation of dispensation reservation of prescription

- Data needed for the cancellation of the dispensation reservation

#### Data on dose dispensing reservation and cancellation of dose dispensing reservation for prescription

- Date of reservation (current date)
- Other necessary data relating to the dose dispensing reservation and the cancellation of dose dispensing reservation

#### Data on the request for renewal of the prescription

- Identifier and name of the organisation that received the request for renewal
- Data on the patient's consent regarding the viewing of other data than data related to the electronic prescription to be renewed
- Patient's mobile phone number
- Message from the registrar

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- Other data needed for the request for renewal

**Data on the processing message regarding the request for renewal (when the request for renewal is denied)**

- Data content of request for renewal of prescription
- Outcome of processing the request for renewal
- Data on the informing of the patient
- Message from the doctor to the pharmacy
- Reasons written by the doctor

**Data on correction and annulment of medicine dispensing (pharmacy)**

- Data content of prescription (a new version of the corrected or annulled dispensation is created, the version of the old dispensation is maintained.)
- Content of the dispensation of prescription

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## Appendix 2

### Disclosure of data in the Prescription Centre

Disclosing data in the Prescription Centre to authorities and other parties:

Section 15 of the Act on Electronic Prescriptions contains provisions on the disclosure of data in the Prescription Centre for purposes of official supervision and scientific research. Data can be disclosed subject to the conditions laid down in the Act:

- to the National Supervisory Authority for Welfare and health (Valvira): data needed for the supervision of health care professionals
- to the Regional State Administrative Agencies: data needed for the supervision of health care professionals
- to the Finnish Medicines Agency (Fimea) prescription given for application for special license under section 21 f of the Pharmaceuticals Act, data needed for instruction on safe and appropriate use of medicines and data needed for supervision under the Pharmaceuticals Act and the Narcotics Act
- to the Social Insurance Institution of Finland (Kela): data necessary for medicine reimbursements under the Health Insurance Act
- for scientific research, by permission from the National Institute for Health and Welfare and in accordance with section 28 of the Act on the Openness of Government Activities
- on request to other parties, summaries of data in the Prescription Centre that can be of significance for medicine safety and for monitoring advantages and costs of pharmaceutical treatments and that do not contain personal data which can reveal the identity of the patient

Data can be disclosed to the aforementioned authorities over a technical communication facility or in writing. In addition to the above, data may be disclosed under other legislation that permits the disclosure of data. The data are provided in writing.

The organisational and technical protections applied when disclosing data shall comply with the provisions of the EU General Data Protection Regulation and other laws governing the processing of personal data.