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1 Custodian	<p>Name Social Insurance Institution of Finland</p> <p>Postal address Postcode Telephone P.O. Box 450 00056 020 634 11</p> <p>Street address Nordenskiöldinkatu 12, 00250 Helsinki</p>
2 Person responsible for register issues or contact person	<p>Name Data Protection Officer for Kanta services asiakaspalvelu@kanta.fi</p>
3 Name of register	<p>Prescription Archive</p>
4 Purpose of processing personal data / purpose of use of the register	<p>According to section 18 of the Act on Electronic Prescriptions (61/2007), the Social Insurance Institution of Finland (hereinafter Kela) is the custodian of the Prescription Archive. Kela is responsible for the availability and integrity of the data in the Prescription Archive, the stability of the data contents and the retention of data, as well as the destruction of data at the end of the retention period.</p> <p>The Prescription Archive is a database into which data in the Prescription Centre (see the privacy policy of the Prescription Centre) is transferred 30 months after the issuing of a prescription until 1 January 2017.</p> <p>Electronic prescriptions recorded in the Prescription Archive and their dispensing data may also be utilised, e.g. when establishing the patient's overall medication regime, in regulatory supervision of social welfare and healthcare services and pharmacies, in decisions concerning benefits by virtue of the Sickness Insurance Act, and in scientific research, reporting and compiling of statistics under the conditions provided by the Act on Electronic Prescriptions.</p> <p>According to the Act on Electronic Prescriptions, electronic prescriptions and the data concerning them shall be stored in the Prescription Archive for 20 years, after which the data will be destroyed.</p>
5 Data content of the register	<p>The Prescription Archive contains electronic prescriptions by virtue of the Act on Electronic Prescriptions, the related dispensing data, and the renewal requests. The data included in the register and the data segments have been compiled in Appendix 1 at the end of this policy.</p>
6 Regular information sources	<p>Prescription Centre (see the privacy policy for the Prescription Centre).</p>
7 Regular disclosure of data and transfer of data to outside the EU or the European Economic Area	<p>Situations of sharing the prescription and dispensing data, the reasons for sharing the data and the method of sharing by virtue of the Act on Electronic Prescriptions and other legislation have been compiled in Appendix 2 at the end of this policy.</p> <p>Data shall not be transferred to outside the EU or the European Economic Area.</p>
8 Principles of protection of the register	<p>The data recorded in the Prescription Archive is confidential data concerning the person's medical status.</p>

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Organisational protection principles

Kela monitors and supervises for its own part that data protection related to its services is realised. Kela has a self-monitoring plan in place to ensure data protection and data security. Kela has appointed a Data Protection Officer for the monitoring and supervision task.

Kela shall provide written instructions on the processing of data in the Prescription Archive and take care of sufficient expertise and competence of its staff when processing the data.

If data is shared with a technical interface, the authority requesting the data must provide an account of how data protection is managed in an appropriate way.

Technical protection principles

The browsing, recording and other processing of data in the Prescription Archive require strong authentication that identifies the processor as well as access rights management related to the system. Kela shall be responsible for its own part for the management of access rights.

Log data is recorded in the Prescription Archive log on all browsing and processing of data in the Prescription Archive.

Physical protection principles

The data recorded in the Prescription Archive is technically protected to prevent editing and deleting.

Kela's IT areas and the physical location of data are in Finland. Kela's technical maintenance staff have restricted access to the IT areas when the management of their duties requires access to these areas.

9 Access to the data

The patient is entitled to inspect their personal data recorded in the Prescription Archive. The request can be submitted on the inspection request form, which is available in social welfare and healthcare units using electronic prescriptions, in pharmacies and in Kela's offices. The request to inspect the data recorded in the Prescription Archive shall be sent to Kela (Registry, P.O. Box 450, 00056 Kela).

The request can be made by telephone or by sending an email to Kela's Registry (kirjaamo@kela.fi). As a rule, the respond to the inspection request is sent free of charge.

10 Right to request rectification of data

Requests for rectifying incorrect data must be addressed to Kela. The operating unit that has recorded the incorrect data must deliver to Kela a written assignment accompanied by a statement of reasons in order to rectify the incorrect data.

If it is not possible to agree to the request for rectification, Kela shall issue a certificate of refusal to the patient. The reasons why the request by the patient or their legal representative was not accepted shall be stated in the certificate of refusal. After receiving the certificate of refusal, the patient may still refer the matter to be dealt with by the competent regulatory authority.

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<p>11 Right to lodge a complaint to the regulatory authority</p>	<p>If the patient deems that the processing of their personal data has breached the applicable data protection regulations (Articles 12–22 of the EU’s general data protection regulation), the patient is entitled to lodge a complaint to the competent regulatory authority. In Finland, the regulatory authority is the Data Protection Ombudsman.</p>
<p>12 Other rights related to the processing of personal data</p>	<p>In My Kanta Pages, the patient can browse the data recorded in the Prescription Archive and view the social welfare and healthcare units and pharmacies that have received the data. My Kanta Pages shows the log data of prescriptions for the previous two years.</p> <p>The patient is entitled to learn who has processed and viewed their personal data recorded in the Prescription Archive by submitting a log data request to Kela.</p> <p>The log data request can be submitted on the log data request form, which is available in social welfare and healthcare units using electronic prescriptions, in pharmacies and in Kela’s offices. The log data request shall be sent to Kela (Registry, P.O. Box 450, 00056 Kela). The request can be made by telephone or by sending an email to Kela’s Registry (kirjaamo@kela.fi). As a rule, the respond to the log data request is sent free of charge.</p> <p>There is no right to obtain log data that is older than two years without a valid reason. For this reason, in the log data request for data recorded in the Prescription Archive, the patient must provide a specific and valid reason for the disclosure of data from the Prescription Archive. The patient must not use or share the log data they have received for any other purpose.</p> <p>If the patient considers on the basis of the log data that their information has been processed without a valid reason, they can request the pharmacy or social welfare and healthcare unit in question for an explanation of the matter.</p> <p>The patient is entitled to receive the same data again if there is a valid reason for it in order to fulfil the patient’s interests and rights. Kela may charge a fee corresponding to the costs of providing the information with regard to information that is provided a second time.</p> <p>The Prescription Archive is a statutory service implemented and maintained by Kela (Act on Electronic Prescriptions). Kela’s operations are based on the national legislation. For this reason, the data subject’s right to erasure of data by virtue of Article 17 of the EU’s General Data Protection Regulation and the data subject’s right to transmit the data from one system to another by virtue of Article 20 shall not be applied to the data recorded in the Prescription Archive.</p>

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Appendix 1

The Prescription Archive contains the following data and data segments:

Prescription data

- Patient data
- Data of the prescriber of the medication
- Organisation data
- Data on issuing the prescription
- Data of the medicinal product and package
- Other data pertaining to the prescription

Dispensing data

- Patient data
- Data on dispensing the medication
- Data on the medicinal product and package during dispensing
- Other dispensing data

Data on cancelling a prescription

- Data content of the prescription, and
- Data on cancelling a prescription

Data on amending a prescription

- Data content of the prescription, and
- Data on amending a prescription
- Data on the person amending a prescription

Data on locking and cancelling a locking of a prescription

- Explanation of the locking
- Explanation of the cancellation of locking
- Other required data related to the locking and its cancellation

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

- Date of reservation
- Reason for the reservation (optional)

Data on the cancellation of a dispensing reservation of a prescription

- Data required for cancelling a dispensing reservation

Data content of a single dose distribution reservation and the cancellation of a single dose distribution reservation of a prescription

- Date of reservation (current day)

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- Other required data related to a single dose distribution reservation and the cancellation of a single dose distribution reservation

Data on a prescription renewal request

- The identifier and name of the organisation receiving the renewal request
- Data on the patient's consent to view the patient's data concerning other than data on an electronic prescription for renewal
- Patient's mobile phone number
- Message from the registrar
- Other data required for the renewal request

Data of the processing message for renewal request (when the prescription renewal has been rejected)

Data content of the prescription renewal request

- Result of the processing of renewal request
- Data on providing the patient with information
- Doctor's message to the pharmacy
- Reasons entered by the doctor

Data of the amending and cancellation of a medicine dispensation (pharmacy)

- Data content of a prescription (a new version is created of an amended or cancelled prescription, the old version of the prescription is retained.)
- Content of the dispensing of the prescription

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Appendix 2

Sharing of data in the Prescription Archive

Sharing of data in the Prescription Archive with the authorities and other actors:

Section 15 of the Act on Electronic Prescriptions provides for the sharing of data in the Prescription Archive for regulatory supervision and scientific research. Therefore, data can be shared under conditions provided in the law:

- Data required in the supervision of healthcare professionals can be shared with the National Supervisory Authority for Welfare and Health (Valvira)
- Data required in the supervision of healthcare professionals can be shared with the regional state administrative agencies
- Data required for a prescription issued in order to apply for a special permit referred to in section 21 f of the Medicines Act, the data required in the guidance of safe and appropriate use of medicines, and the data required in the supervision according to the Medicines Act and the Narcotics Act can be shared with the Finnish Medicines Agency (Fimea).
- Data required for the processing of medicine reimbursements according to the Sickness Insurance Act can be shared with Kela
- For scientific research by virtue of a permit issued by the National Institute for Health and Welfare in accordance with section 28 of the Act on the Openness of Government Activities
- summaries of data in the Prescription Archive that may be important when studying pharmaceutical safety and the benefits and costs of drug treatment and does not include personal data that would reveal the patient's identity upon request with other actors.

The data may be shared with the above-mentioned authorities via a technical interface or in writing. In addition to the above, data may be shared by virtue of other legislation entitling the sharing of data. The data is provided in writing.