



PATIENT INFORMATION ON CROSS-BORDER ELECTRONIC PRESCRIPTION SERVICES FOR PERSONS ARRIVING IN THE REPUBLIC OF LITHUANIA

This document provides information about the cross-border exchange of electronic prescription data and data management and protection practices in the event of medicinal products being sold in the Republic of Lithuania.

1 What is the eHealth Digital Service Infrastructure?

The electronic health digital services infrastructure ('eHDSI') provides secure and easy access to medical data for healthcare professionals involved in medical treatment and qualified pharmacists involved in the sale of medicinal products. eHDSI services may also be recognised as the brand 'MyHealth@EU'. This infrastructure provides healthcare professionals with electronic access to medical data on EU residents anytime and anywhere within the EU. This is done via a secure data portal provided by the eHealth National Contact Point ('eHealth NCP') designated by each Member State.

The data from the ePrescription made out to you will be transferred from the information system of the healthcare institution or the national electronic health services and cooperation infrastructure information system to the pharmacy operating in Lithuania via the eHealth NCP of the country that issued the ePrescription.

The functions of the Lithuanian National eHealth Contact point ('LNCP') are performed by the State Enterprise Centre of Registers (*Registrų centras*). Each country is responsible for the activities of the eHealth NCP in that country.

2 What are the categories of health-related personal data?

Nationals of another EU Member State (with which Lithuania exchanges ePrescription data) can purchase a medicinal product in Lithuania using an electronic prescription ('ePrescription') issued in their Member State, and can find the relevant document on the sale of the medicinal product effected in Lithuania in their patient account in the information system of a healthcare institution or the national electronic health services and cooperation infrastructure information system.

The ePrescription contains all essential information on the secure sale of medicinal products to the patient.

Information contained in the ePrescription

- Information on the healthcare institution, specialist and patient:
 - Information on the patient to whom the ePrescription was issued:
 - full name;
 - patient identification number(s);
 - date of birth;
 - sex;
 - information on the healthcare specialist who issued the patient with the ePrescription:
 - full name;
 - identification number;
 - specialisation of the healthcare professional;
 - contact telephone number;
 - information on the healthcare institution at which the ePrescription was issued;
 - name:
 - identification number;
 - country;
 - address;





- contact telephone number;
- competent institution (data controller/processor):
 - name;
 - identification number;
- ePrescription data:

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- Prescription information:
 - ePrescription identification number;
 - date of issue of ePrescription;
 - specific name of the medicinal product, where prescribed under a specific trade name;
 - common name of the medicinal product;
 - strength of the medicinal product;
 - pharmaceutical form of the medicinal product;
 - ATC 5th level code and its value;
 - packet size of the prescribed medicinal product;
 - number of packets of the prescribed medicinal product;
 - information on the use of the medicinal product:
 - route of administration of the medicinal product;
 - single-dose medicinal product;
 - frequency of use of the medicinal product;
 - duration of treatment;
 - against 'May the medicinal product be sold under another specific name?' enter 'yes', or 'no' if the ePrescription indicates a specific name for the medicinal product;
 - information for the patient information in free text that may be provided in another EU language;
 - information for the qualified pharmacist, where the specialist at the healthcare institution gives such information - information in free text that may be provided in another EU Language.

Information on the dispensing (sales) document:

- Information on the pharmacy, qualified pharmacist and patient:
 - Information on the patient to whom the medicinal product was dispensed (sold):
 - full name;
 - identification number;
 - information on the qualified pharmacist who sold the medicinal product:
 - full name;
 - identification number;
 - Information on the pharmacy at which the medicinal product was sold:
 - name;
 - identification number;
 - address;
- Details of dispensing (sales) document:
 - \circ $\;$ information on the sale of the medicinal product:
 - identification number of the dispensing (sales) document;
 - date of sale;
 - identification number of the ePrescription on the basis of which the sale was made;
 - exact name of the medicinal product;
 - ATC 5th level code and its value;
 - strength of the medicinal product;
 - packet size of the medicinal product sold;
 - number of packets of the medicinal product sold;

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- pharmaceutical form of medicinal product.
- against 'Medicinal product name has changed', if the patient has an electronic prescription issued in another EU country that contains the entry 'Is the sale of the medicinal product under another specific name permitted?' to which the answer is 'Yes', medicinal product sold under another specific name.

Only valid ePrescriptions and their data are transmitted from another EU country via the eHealth NCP to a pharmacy operating in Lithuania.

Qualified pharmacists in Lithuania will be able to access a Lithuanian translation of an ePrescription issued in another EU country along with the original version of the prescription in the language of the country that issued the ePrescription, in PDF format, using the pharmacy's information system or Lithuania's Electronic Health Services and Cooperation Infrastructure Information System ('ESPBI IS') (via the eHealth NCP).

When selling medicinal products, the qualified pharmacist enters the relevant data into the pharmacy's or the ESBIS information system and completes the sale of the medicinal product. Information on the sale of medicinal products will be sent from the ESPBI IS via the LNCP to the eHealth NCP of the other EU Member State.

3 What is the legal basis for the processing of your personal data?

MyHealth@EU services are provided in Lithuania on the following basis:

• Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

In Lithuania, the processing of personal data is carried out by way of discharge of a legal obligation and exercise of delegated official authority (Article 6(1)(c) and (e) and Article 9(2)(g), (h), (i) and (j) of the General Data Protection Regulation). The processing of personal data is established by:

• Paragraphs 13 to 16 of the provisions on the information system for electronic health services and cooperation infrastructure approved by Government Resolution No 1057 of 7 September 2011 approving the provisions on the information system for electronic health services and cooperation infrastructure.

When you purchase medicinal products in Lithuania, your personal data will be processed in accordance with the EU General Data Protection Regulation (GDPR) and Lithuanian legislation.

4 Who can use the cross-border ePrescription?

Patients from another EU country providing the MyHealth@EU cross-border ePrescription service who go to a pharmacy operating in Lithuania, and who have given their consent to share their personal data and provided a personal identity document and/or another document with personal identification number(s) or mandatory information to be supplied in accordance with the requirements of that country, allowing the qualified pharmacist in Lithuania to perform a patient search in the pharmacy's or Lithuania's ESPBI information system. For information on the EU countries with which Lithuania exchanges ePrescription data, see the list of countries for cross-border eHealth data exchange:

https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-healthservices_lt.

5 Why are your personal data being processed?

Data from ePrescriptions and the pharmaceutical dispensing (sales) document are processed to allow the exchange of data when a patient from another EU country wishes to buy a medicinal product in Lithuania.





Data relating to your health (ePrescription data) may also be processed for reporting and statistical purposes, and for scientific research and data archiving purposes. If you wish, an invoice may be issued for the medicinal product sold, using the relevant information on the dispensing document.

6 Who manages your health-related data and has access to them? (recipients of personal data)

The only people who will be able to access your personal data in Lithuania and other EU Member States are authorised and identifiable healthcare specialists who have the right to issue an ePrescription and qualified pharmacists having the right to dispense (sell) medicinal products. These specialists have undertaken to guarantee the confidentiality of personal data. The confidentiality obligation incumbent upon healthcare professionals and qualified pharmacists is based on law and professional ethics.

When data are transferred to another EU country using the MyHealth@EU service, each data recipient takes responsibility for the processing of these data as part of their data processing activities.

This responsibility is assumed by the following data recipients:

- the healthcare provider that issued the ePrescription;
- the LNCP;
- the eHealth NCP of the EU Member State to which the eHealth data are transferred;
- the pharmacy in which the sale of the medicinal product takes place.

7 Where are your personal data stored and for how long?

Your personal data may be kept in the information systems of the healthcare institutions of the patient's country of residence and in the information systems of the country in which the medicinal product was sold. Logs of cross-border exchanges of data are kept at the eHealth NCP.

Time-limits for the storage of data in Lithuania are as follows:

ESPBI IS data are collected and stored in the ESPBI IS data repository and the ESPBI IS data archive in accordance with the procedure laid down by Lithuania's senior archivist. Patient data are stored in the ESPBI IS data repository during the patient's lifetime and for three years after their death, at which point the personal data are automatically transferred to the ESPBI data archive.

Personal data in the ESPBI IS data archive are kept for 75 years from the time of their transfer from the ESPBI IS data repository. At that point, by decision of the committee set up by the ESPBI controller, data in the ESPBI archive are deleted if they are no longer needed for ESPBI IS purposes, or transferred to the national archive in accordance with the procedure laid down in the Lithuanian Law on documents and archives and in other items of legislation. The ESPBI IS data archive is destroyed or transferred to the national archive and archive in accordance with the procedure laid down in the Lithuanian Law on documents and archives and other items of legislation.

8 Your rights as a provider of personal data

As a data subject, you have the right to contact the Lithuanian Ministry of Health or the Centre of Registers (for contact details, see section 9 of this document) in respect of questions relating to the processing of your personal data, in other words, you have the right to:

- obtain information on the processing of data (GDPR Articles 13 and 14);
 - access your data (GDPR Article 15);
 - have data rectified (GDPR Article 16);
 - have processing restricted (GDPR Article 18). Note: This right may be exercised even if just one of the conditions referred to in GDPR Article 18(1) is met.





The patient has the right to lodge a complaint with the competent data protection authority. In Lithuania this is the State Data Protection Inspectorate (*Valstybinė duomenų apsaugos inspekcija*): <u>https://vdai.lrv.lt/lt/veiklos-sritys-1/skundu-nagrinejimas/</u>.

A list of all data protection authorities in the EU Member States can be found here: <u>https://www.edpb.europa.eu/about-edpb/about-edpb/members_en</u>.

9 Contact information.

- LNCP: State Enterprise Centre of Registers, Studentų g. 39, Vilnius, LT-08106, email: <u>e.sveikata@registrucentras.lt</u>, tel.: +370 5 236 4577 (Opening hours: Monday to Thursday 08:00 to 17.00, Friday 08:00 to 16:00);
- Data Protection Officer at the Lithuanian Ministry of Health, Vilniaus g. 33, LT-01402 Vilnius, email: <u>duomenuapsauga@sam.lt;</u>
- Data Protection Officer at the State Enterprise Centre of Registers, Studentų g. 39, Vilnius, LT-08106, email: <u>duomenusauga@registrucentras.lt</u>;
- Data Protection Authority in Lithuania: State Data Protection Authority, L. Sapiegos g. 17, LT-10312 Vilnius, email: ada@ada.lt, tel.: +370 5 212 7532 (opening hours: Monday to Thursday 09:00 to 11.00 and 13.00 to 15.00).

More information on cross-border exchanges of data can be found here: <u>https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-</u>services lt.





INFORMATION ON SERVICES AND PROCEDURES IN THE REPUBLIC OF LITHUANIA

Member State	Lithuania
Service provided by the State	Cross-border ePrescription and the sale of an ePrescription medicinal product.
Data exchanged	Data on the cross-border ePrescription and on the document relating to the dispensing (sale) of an ePrescription medicinal product. More information on the data used in this service can be found in section 2 of this document.
Government role in the exchange of data	To transfer information on a medicinal product sold under a cross-border ePrescription to the country which issued the patient with the ePrescription.
Legal Basis	To use this service, you need to have given your consent to the transfer of your health-related personal data (ePrescription data) to other EU countries and to the use of MyHealth@EU services. More information on the applicable items of legislation/provisions/directives can be found in section 3 of this document.
Restriction on access to certain data	You can restrict the transfer of health-related personal data (ePrescription data) to another EU country by opting out via the ESPBI IS patient portal (<u>https://www.esveikata.lt/</u>).
Purpose of data use	Basic purpose of data use: Sale of medicinal products
Data retention	ESPBI IS data are collected and stored in the ESPBI IS data repository and the ESPBI IS data archive in accordance with the procedure laid down by Lithuania's senior archivist. Patient data are stored in the ESPBI IS data repository during the patient's lifetime and for three years after their death, at which point the personal data are automatically transferred to the ESPBI data archive. More information on data retention can be found in section 7 of this document.
Data controller	Ministry of Health of the Republic of Lithuania Address: Vilniaus g. 33, LT-01402 Vilnius email: <u>ministerija@sam.lt</u> Tel.: +370 800 66 004 (freephone) +370 5 268 5110
Data processors	Main data processor: State Enterprise Centre of Registers Address: Studentų g. 39, LT-08106 Vilnius email: <u>info@registrucentras.lt</u> Tel. +370 5 268 8262 Other processors:





Member State	Lithuania
	Accredited Lithuanian healthcare institutions Accredited Lithuanian pharmacies
Data Protection Officer	Data Protection Officer at the State Enterprise Centre of Registers Address: Studentų g. 39, LT-08106 Vilnius email: <u>duomenusauga@registrucentras.lt</u>