

Ministry of Health of the Republic of Latvia

Brīvības iela 72, Rīga, LV-1011, tālr. 67876000, fakss 67876002, e-pasts ym@ym.gov.ly, www.ym.gov.ly

Rīgā

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Dr. Andoulla Eleftheriou President Cyprus Alliance for Rare Diseases P.O.Box 28807, 2083 Strovolos 31 Ifigenias, 2007, Strovolos Cyprus

Re: Treatment of patients with Rare Diseases in small EU Member States

Dear Dr. Eleftheriou,

In response to your letter of 3 February 2017 I can provide the following information regarding Latvia.

Currently Latvia has no national legislation on the process for designating Centres of expertise (CoE). However, we have amended the law that provides the Cabinet of Ministers to determine the requirements for medical institutions (structural units of university hospitals or specialized hospitals) that wish voluntarily to join the European reference networks and the procedures by which the medical institutions join the European reference networks. CoE will comply with the currently existing minimum requirements for medical institutions (defined in the Regulation of the Cabinet of Ministers of the Republic of Latvia No.60 "Regulations Regarding the Mandatory Requirements for Medical Treatment Institutions and their Structural Units" (adopted on 20 January, 2009), as well as with the requirements prescribed by the European Commission Delegated Decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (2014/286/EU).

Several medical centres that fulfil this role are currently recognized by reputation only. For example, the Children's Clinical University Hospital provides genetic services, as well as services for children with haematological, oncological and endocrine diseases. Riga East Clinical University Hospital has a specialized clinic of chemotherapy and haematology, in which patients with haemophilia A and B, factor XII deficiency and von Willebrand disease receive diagnostics and treatment. Rare oncological diseases, e.g. Burkitt's lymphoma, Langerhans cell histiocytosis. Mantle-cell non-Hodgkin's lymphoma, multiple endocrine neoplasia, Ewing's sarcoma, Wilms' tumour. Waldenstrom's macroglobulinaemia and others can be treated in this hospital as well. Pauls Stradins Clinical University Hospital provides services in different rare disease areas, such as cardiology, angiology, pulmonology, nephrology, endocrinology, gastroenterology, oncology and ophthalmology. Latvian Hypertension Centre is a part of Centre of Cardiology of Latvian University located in Pauls Stradins Clinical University Hospital

In addition, the Children's Clinical University Hospital Eye clinic and Haematooncological clinic from December last year have been recognized as health care providers in EU.

The National Health Service (NHS) is the operating direct administrative institution subordinate to Ministry of Health and its scope of activities is to:

- inform the society about the available health care services and the procedure according to which the latter can be received, as well as advise the country's residents on their rights while receiving health care services;
- in the regression procedure to recover the financial means for course of treatment for persons, provided that the present course of treatment is the consequence of an unlawful activity, inactivity or criminal offence;
- ensure the execution of the international liabilities in the implementation of the availability of health care services, as well as in the administration of the State budgetary funds prescribed for health care;
- cooperate with foreign and international institutions, as well as to exchange information in the field related to the service.

The Cross-border Healthcare Directive envisages reimbursement for the expenses for scheduled healthcare services received in another EU member state, Norway, Iceland, Switzerland and Liechtenstein (the inhabitants of Latvia may apply for a reimbursement in accordance with the tariffs for the healthcare services effective in Latvia).

• When receiving a healthcare service in another member state, the patient shall receive from their country the amount fixed for the service in the home country of the patient (here – in Latvia), but not exceeding the amount the patient has actually paid for such service.

- Only the healthcare services covered from the national budget in the home country (here Latvia) can be reimbursed. The patient shall arrange and pay for the transportation and accommodation as well as pay to the provider of the healthcare services in advance.
- A special permission is required for some services in other EU member states, Norway, Liechtenstein, Iceland and Switzerland.

The National Health Service shall decide on the issue of the prior authorization for the following scheduled healthcare services in another EU, EEA (Norway, Iceland, Liechtenstein) member state or in Switzerland:

- endoprosthesis replacement of the large joints in an in-patient facility;
- cardiac surgery treatment in an in-patient facility (e.g., myocardial revascularisation; coronary artery bypass surgery, mammaro-coronary bypass surgery; cardiac tumour surgery; valve plastic surgery; correction of congenital cardiac conditions, etc.);
- medical rehabilitation in an in-patient facility;
- surgical services in ophthalmology (such as cataract, glaucoma surgeries);
- medical fertilisation.

The National Health Service shall refuse to issue the prior authorization:

- for healthcare services provided within clinical studies or involving the use of an experimental medical technology;
- in cases when the healthcare service can be received in the territory of the Republic of Latvia within the following timelines:
- endoprosthesis replacement of the large joints in an in-patient facility and medical fertilisation 5 years;
- cardiac surgery treatment in an in-patient facility and medical rehabilitation in an in-patient facility 12 months;
- surgical services in ophthalmology 24 months.

To obtain a prior authorization for an EU, EEA member state or Switzerland and in order to be reimbursed for the treatment expenses, the following documents shall be submitted to the Central Office of the National Health Service:

- the application containing the name, surname, identity number, address, telephone number or e-mail address of the individual, the healthcare service for which the advance permission is requested, the state in which the individual plans to receive the healthcare service;
- the referral issued by the family doctor (GP) or specialist;
- in case it is planned to receive a healthcare service in an in-patient facility, the conclusion of the panel of doctors of the respective medical institution with information about the healthcare service to be provided to the individual;
- the statement issued by the medical institution regarding inclusion of the individual into the waiting list for the respective healthcare service (with

specified time when the individual would be able to receive the necessary healthcare services in Latvia).

To be reimbursed for the expenses for healthcare services in an EU, EEA member state or in Switzerland (covered from the personal resources), the following documents shall be submitted to the Central Office of the National Health Service:

- the application containing the name, surname, identity number, address, telephone number or e-mail address of the individual, the individual's bank account details; the state in which the healthcare services have been received; the name, registration number and address of the healthcare service provider; a description of the reasons for the receipt of the healthcare services in the other EU, EEA member state or in Switzerland. If the individual requests that they be reimbursed for their expenses for healthcare services received based on the prior authorization issued by the National Health Service, the date and number of the decision shall be provided;
- the documents confirming the payments (where the payer can be identified);
- the documents issued by the healthcare service provider and containing the healthcare services provided to the individual; the time of provision of the healthcare services; the prices of each of the healthcare services provided to the individual, the proof of payment for the provided healthcare services, and a notarised translation of these documents;
- the prescription or the referral issued by the family doctor (general practitioner) or specialist (no referral is necessary if the patient has turned to a directly accessible specialists) if the individual has received scheduled healthcare services (including those according to the special permission);
- a confirmation that the individual is not insured under another social insurance plan.

Like until now, the residents of Latvia may receive the European Health Insurance Card (EHIC) to be able to travel to other EU member states, Liechtenstein, Norway, Iceland or Switzerland and, if necessary, produce the EHIC in order to receive emergency and necessary medical care on the same conditions as such care is provided to the residents of the respective state.

The European Health Insurance Card (EHIC) is a joint document for all European Union, European Economic Area countries and Switzerland Confederation that confirms the rights of citizens to receive state-funded emergency and necessary healthcare services to the same extent that it has secured the country's population.

In order to ensure the transfer of rights to health care services set by EU legal acts to another EU, EEA Member States (Norway, Liechtenstein and Iceland) or Switzerland, namely the right to have access to the State funded health care services being in other EU, EEA member States or Switzerland, in the framework of EU, the documents of a single sample are used for receiving health care services

in a member State, which is not subject to the social security system. These documents are a confirmation of the fact that the Member State, whose competent authority has issued this document, undertakes covering the costs of another Member State for the health care services provided in its territory. Latvian competent authority, which issues such documents, is the National Health Service.

- Form S1 "Certificate of the right to receive health care services" (hereinafter referred to as the Form S1) that provides the person with possibility to receive health care services guaranteed in the indicated State for persons insured within the Latvian social security system and retired persons, as well as for the family members of these persons living in another EU or EEA Member State or Switzerland;
- Form S2 "Certificate of the right to receive scheduled treatment" (hereinafter referred to as the Form S2) that provides the person with possibility to receive the indicated scheduled treatment in the indicated State and according to the indicated deadline for persons insured within the Latvian social security system that need scheduled health care services that cannot be provided in Latvia;
- Form S3 "Certificate of the right to receive medical treatment for retired frontier workers in the State where he was employed" that provides such person with the right to complete the treatment indicated in the Form in the State indicated in the Form for retired frontier workers;
- European Health Insurance Card (hereinafter referred to as EHIC) or EHIC replacement certificate which provides for the right to receive urgent or necessary medical assistance during short-time residence in another EU, EEA Member State or Switzerland for persons insured within the Latvian social security system.

In 2013, the following amendments were made in the regulatory enactments of Latvia in relation to the application procedure of provisions of EU social security coordination:

- 1) On 17/12/2013, the Cabinet of Ministers adopted new Regulation No.1529 "Procedure of Funding of the Health Care Organisation"; which resulted in cancellation of the Cabinet Regulation No.1046 "Procedure of Organisation and Funding of the Health Care" of 19/12/2006. These amendments have helped to improve the structure of regulatory framework, the application procedure of provisions for EU social security coordination has not been substantially changed;
- 2) Cabinet Regulation No.1529 "Procedure of Funding of Health Care Organisation" of 17/12/2013 is the legal framework related to the procedure that

can help a person insured within the Latvian social security system to require compensation of expenses for cross-border health care when such person has gone to another State to receive health care services (this legal framework has been taken from the Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare).

Please, do not hesitate to contact us if any additional information is necessary.

Yours sincerely,

Kārlis Ketners

State Secretary