Judgment by the Constitutional Court of the Republic of Latvia
On Behalf of the Republic of Latvia
Riga, 7 January 2010
Case No. 2009-12-03

The Constitutional Court of the Republic of Latvia composed of the Chief Justice of the Court session Gunārs Kūtris, and a panel of judges Kaspars Balodis, Aija Branta, Juris Jelāgins, Kristīne Krūma, Viktors Skudra

Having regard to the Department of Civil Cases of the Senate of the Supreme Court application

Based on Article 85 of the Constitution of the Republic of Latvia and Clause 3 of Section 16, Clause 3 of the First Paragraph of Section 17, Section 19^1 and 28^1 of the Constitutional Court Law

On 15 December, 2009 heard the matter by way of written procedure

On the conformity with Article 93 and 110 of the Constitution of the Republic of Latvia of Clause 92 second sentence's words "within the granted limits of medication purchase", Clause 94's words "with the exception of mentioned case in the Regulation Paragraph 100^1", Clause 100's words "not more than amount of 10 000 Latvian Lats (hereinafter - LVL) for one patient in 12 months " and the second sentence of Clause 100^1 of the Cabinet of Ministers Regulations No. 899 of 31 October 2006 on the procedures for compensating purchase costs of the medication and medical equipment for out-patient treatment.

Procedure and facts:

1. On 10 April 1997, the Parliament of the Republic of Latvia (hereinafter – the Saeima) adopted the Pharmaceutical Law. Section 2 of this Law (in the version of 16 April 2003) established its purpose: "To regulate the activities of natural and legal persons in the field of pharmaceuticals, as well as to ensure the manufacture and distribution of medicinal products which are qualitative, medically appropriate and of an appropriate prophylactic, treatment and

diagnostic level". Section 5 of this Law defines the area of responsibilities for the Cabinet of Ministers.

On 15 December 2005, the Saeima adopted the Law on Amendments to the Pharmaceutical Law. Section 5 of that Law was supplemented with Clause 20 which authorizes the Cabinet of Ministers to define "the procedures of compensating purchase costs of the medication and medical equipment for out-patient treatment".

2. In accordance with Clause 20 of Section 5 of the Pharmaceutical Law, on 31 October 2006 the Cabinet of Ministers adopted Regulations No. 899 on the procedures of compensating purchase costs of the medication and medical equipment for out-patient treatment (hereinafter – the Regulations No. 899).

Chapter XII of those Regulations determines procedures of compensating purchase costs of the medication and medical equipment for individuals. Clauses 92, 94, 100 and 100^1 included in those Regulations (in the version of the Cabinet of Ministers Regulations No. 219 of 27 March 2007) establish:

"92. The Health Payment Centre, on the basis of the submission of a person, to which a decision of the doctors' council of the relevant treatment field has been appended, is entitled to take a decision regarding the reimbursement of expenditures for the acquisition of medicinal products and medical devices for individual patients. The referenced expenditures shall be reimbursed within the scope of the funds granted for the reimbursement of expenditures for the acquisition of medicinal products in the following cases:

92.1. The diagnosis is not included in Annex 1 to these Regulations, and in the treatment of the respective disease it is not possible to maintain the vital functions of the patient without the use of the respective medicinal products (medical devices are not paid for in the specific case referred to in this Sub-paragraph); and

92.2. The diagnosis is included in Annex 1 to these Regulations, and no reimbursable medicinal products and medical devices are appropriate for the

maintenance of vital functions (use of such medicinal products and medical devices that are not included in the list of reimbursable products for the respective diagnosis shall be necessary).

94. In the case referred to in Sub-paragraph 92.1 of these Regulations the Health Payment Centre shall take a decision regarding the reimbursement of expenditures for the acquisition of medicinal products or medical devices in the amount of 100%, except for the case referred to in Sub-paragraph 100^1 of these Regulations.

100. The Health Payment Centre shall reimburse expenditures for the acquisition of medicinal products and medical devices in the cases provided in this Chapter up to amount of not more than LVL 10 000 for one patient within 12 months.

100^1 If the intended expenditures exceed the amount referred to in Paragraph 100 of these Regulations, the Health Payment Centre shall indicate the reimbursement of expenditures for one packaging of medicinal products in the decision regarding the reimbursement of the medicinal products. The difference between the price of one packaging of the medicinal products and the reimbursement amount indicated in the decision of the Health Payment Centre shall be covered by the patient upon the receipt of medicinal products in a pharmacy."

3. On 19 April 2007, G. Z. (at that time 3 years old) was diagnosed with type 1 Gaucher's disease by the Medical Genetics doctors council in the Medical Genetics Clinic of the State limited liability company the University Children's Hospital (hereinafter – the University Children's Hospital). (See page 48 volume 1 of the case materials).

On December 2007 and November 2008, the parents, on behalf of G. Z., claimed for compensation of medication purchase costs. Two administrative cases have been prosecuted due to decisions the Authorities have made regarding those claims. Hearing the first of the above mentioned two cases

under the cassation procedure, an application has been submitted on prosecuting this case in the Constitutional Court. At first the required medication for G. Z. was paid by donations, however, later the reimbursement for the medication was paid under the temporary regulations set by the Court of Administrative Cases.

Facts of the Case in chronological order are as follows:

On 11 October 2007, the doctors' council of the Medical Genetics Clinic confirmed G.Z.'s diagnosis. In the aforementioned decision it is pointed out that Gaucher's disease is progressing and because of this disease, metabolism accumulates by-products in liver, spleen, red bone marrow and bones. If it is not treated, it may cause ruptured spleen, bleeding, higher risk of infection and bone crisis (regular osteoporotic fractures), and extended hospitalization and early death may be expected. Gaucher's disease can be successfully treated with Cerezyme (manufactured by Genzyme Therapeutics, USA). The course of treatment is life-long. This medication is not included in the Medication Register of the Republic of Latvia, but this medicament is the only approved drug for treating children with Gaucher's disease (See Page 46-47 of Volume 1 of the Case Materials).

G.Z.'s parents, on behalf of their child, approached the Health Compulsory Insurance State Agency (now Health Payment Centre; hereinafter - HCISA) asking for 100% compensation for the purchase cost of Cerezyme.
Reviewing the aforementioned application, HCISA estimated that if G.Z. takes these drugs, then 12 month course of treatment would cost 81 900 Latvian Lats. On 11 December, HCISA passed Resolution No. 6/1-1-10/7673 where it was stated to compensate for G.Z. the purchase costs of the medicament Imigluserase (Plac. Cerezyme 200V) for a 12 month course of treatment (120 packs) from 17 December 2007 till 16 December 2008. By this Resolution the maximum sum of money for reimbursement of 1 pack is LVL 83.33 (with VAT of 5%) and a maximum amount of money for reimbursement of LVL 10 000. The difference between the reimbursable sum of money of purchase costs for the above mentioned 1 pack indicated in that Resolution and the

approved price of 1 pack of this medication in a pharmacy is LVL 599.17, which are paid by a patient at the moment of receiving the medication in a pharmacy. HCISA refers to the impugned regulations in that Resolution.

The aforementioned Resolution was contested in the Ministry of Health asking for 100 % compensation of medicament Cerezyme purchase costs. By the Ministry of Health adopted Resolution of 4 April 2008 the above mentioned amount claimed was rejected and the HCISA Resolution remained valid.

On 6 May 2008, an application was submitted to the Regional Court of Administrative Cases by G.Z. In that application, a claim was made for a repeal of the aforementioned Resolution adopted by the Ministry of Health and that HCISA must be instructed to pass a resolution on 100% compensation of Cerezyme purchase costs for 12 month course of treatment from 17 December 2007 till 16 December 2008. In the application it is stated that resolutions adopted by the Ministry of Health and HCISA violate the guaranteed rights to life as stated in Article 93 of the Constitution of the Republic of Latvia (hereinafter – the Constitution) and are in contradiction with proportionality principles. All persons diagnosed with chronic and life-threatening disease are in equal positions. Nonetheless, those persons with such diagnosis were treated in a different and unreasonable way by the State authorities, because their diagnosis is not included in Appendix 1 of the Regulations No. 899 (therefore, required medication is not reimbursable). Based on the aforementioned application, the Administrative Case No. A42561808 (hereinafter – the First Administrative Case) was prosecuted.

On 29 January 2009, the Regional Court of Administrative Cases heard the appeal filed by the Ministry of Health. The Court held that a dispute does not exist about G. Z.'s diagnosis and its influence neither on his/her health, nor about the required medication and the therapeutic efficiency. Furthermore, a dispute does not exist about implementing preconditions of medication reimbursement for individuals under the procedure established in Clause 92.1 of the Regulations No. 899. In the particular Case a dispute exists whether the specified amount for compensation within 12 months as defined in Clause 100

and procedure established in Clause 100^1 of the Regulations No. 899 is applicable in the particular case, when awarding the reimbursement.

The court concluded that the Administrative Deed as far as it is compliant with the above mentioned regulations shall be considered as mandatory. The Institution has distinctly applied the legal order established in Clause 100 and 100^1 of the Regulations No. 899 while issuing the particular Administrative Deed.

The court indicates that if legal provisions define issuing of mandatory Administrative Deed and the Institution properly applies these regulations while issuing such Administrative Deed, which disproportionally limits the rights of individual, then it is a mistake of the Legislator, not the Institution. According to the Latvian legislation this kind of mistake is resolved in two ways. First of all, such mistakes of the Legislator can be fixed by the Constitutional Court. Second of all, the Administrative Court is authorized to adjust the legislation by eliminating the issue of mandatory Administrative Deed.

By reviewing the listed arguments for violating the right to life, the Regional Court of Administrative Cases pointed out that the right to life includes the State's negative responsibility (to not kill person unless it is extremely necessary) and positive responsibilities (to protect a person's life from unwarranted State actions, as well as other persons malicious intents). The State objectively cannot be responsible for illness of a person and the natural consequences of that illness. This particular human right by its content is not applicable to the special conditions of this case.

The Regional Court of Administrative Cases declined the application submitted on behalf of G. Z for issuing a beneficial Administrative Deed, which would impose the reimbursement of the required medication of 100%.

On behalf of G.Z. a cassation complaint over the rejected application was submitted indicating that the Court has unreasonably applied Clause 100 of the

Regulations No. 899. It should be applied according to justice and proportionality principles. The Court has applied the above mentioned clause by not considering that the G. Z.'s right to get free of charge medical treatment was discriminated.

On 21 May 2009, in accordance with the cassation complaint the Department of Civil Cases of the Senate of the Supreme Court heard the First Administrative Case under cassation procedure. The Court was uncertain about the compliance of the words "within the granted limits of medication purchase" mentioned in the second sentence of Clause 92, Clause 94 to the extent it states "with the exception of the mentioned case in the Regulation Paragraph 100^{1}", the amount mentioned in Clause 100 as "not more than amount of LVL 10 000 for one patient in 12 months" and the second sentence of Clause 100^{1} of the Regulations No. 899 (hereinafter – the impugned regulations) with Article 93 and 110 of the Constitution. By concluding that the impugned regulations are required in order to continue hearing this matter, the Department of Civil Cases of the Senate of the Supreme Court ruled to submit the particular application to the Constitutional Court and terminate the legal proceedings of the First Administrative Case until the Constitutional Court verdict comes into effect.

On 18 August 2009, the Regional Court of Administrative Cases ruled to terminate the legal proceedings in the Second Administrative Case until the Constitutional Court verdict came into effect.

4. The Claimant - the Department of Civil Cases of the Senate of the Supreme Court (hereinafter – the Senate) in its application indicates that the impugned regulations are not in compliance with Articles 93 and 110 of the Constitution.

Referring to the work practice of Federal Court of Germany, the Senate points out that the rights established in Article 93 of the Constitution might be violated also in situations when insufficient health care is provided. In the application is indicated a conclusion of the European Court of Human Rights (hereinafter - ECHR) that under certain conditions action or inaction of

institutions may cause the State's responsibility for violation of Article 2 of the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter – the Convention). (See ECHR judgment of 21 March 2002 in Case *Nitecki* v. *Poland*, Application No. 65653/01).

The Senate emphasized that not only is Regulation No. 899 related to health-care, but also Chapter XII of those Regulations directly applies to a person's right to life. Deprivation of life, when it is beneficial to other people's basic rights, can only be limited by cases defined in Second Paragraph of Article 2 of the Convention. The impugned regulations cannot be considered as one of those cases.

If rights guaranteed under the Constitution would be declared not absolute and could be imposed with restrictions in order to protect other constitutional values, then, in the Senate's opinion, it would only be possible under rules of a democratic country. Wherewith, the Constitutional Court should verify whether the incorporated human rights restrictions in the impugned regulations are justifiable with a legitimate cause and is commensurate with the particular cause.

The Senate states that the Constitutional Court, while hearing Case No. 2008-37-03, has not taken into account the total amount of the State budget, but only the allocated budget for health area. The reimbursement of expenditures for the acquisition of medicinal products and medical devices for individuals is not based on the high costs of such medicinal products and medical devices and the impact it may have on the State budget. The Senate claims that it is based on the fact that the diagnosis has still not been registered in the Annex of the Regulations No. 899 and the required medication is not included in the Register of Reimbursable Medication.

The Senate in its application indicates that a dispute does not exist and that by not receiving required medicament such patients would die. The Senate considers that the State should review therapeutic efficiency of medicaments, probable lifespan and economic efficiency of medicaments for each individual

patient. The procedure of the medicament reimbursement does not lower medicament costs, but, on the contrary, increases prices, distorts competition and intensifies corruption.

The Senate agrees with the opinion stated in Case No. 2008-37-03 that the society benefits from the impugned regulations, which allow to have wider access to health care. The Senate states that people, whose diagnosis is not officially acknowledged by the State, are still a part of society and their rights to life and health should not be restricted. Moreover, restrictions on the minority in a society cannot be justified on the ground that the social, economic and cultural rights of the majority are protected.

Referring to Article 6 of the UN Convention on the Rights of the Child of 20 November 1989 (hereinafter – the UN Convention) the Senate emphasizes that the child's right to life is inalienable and the State has an obligation to provide maximum survival chances and healthy development possibilities.

The Senate highlights that Article 110 of the Constitution delegates a particular responsibility to the State to help children and disabled persons, as well as it defines that the Legislature, while establishing judicial procedure, should take into account the age of a patient whose life depends on the required medication. The impugned regulations restrict rights of these children without reason.

In the application is stated that in the Constitutional Court judgment in Case No. 2008-37-03 the Constitutional Court has not considered conformity with Articles 93 and 110 of the Constitution of the impugned regulations. Moreover, the facts of G.Z. administrative case propose a different way to look at the proportionality of basic rights.

The Senate does not deny that in the above mentioned case the Constitutional Court has incorporated arguments which are related to the compliance of the impugned regulations with the right to life. The Senate, however, considers

that the Constitutional Court has not sufficiently and thoroughly analyzed the violation of right to life in the aforementioned arguments.

5. The Institution that issued the impugned regulations (the Cabinet of Ministers) does not agree with the Senate statement that the impugned regulations are compliant with Articles 93 and 110 of the Constitution. The Cabinet of Ministers asks to decline the application.

5.1 The Cabinet of Ministers interprets Article 93 of the Constitution in connection with Article 2 of the Convention. With a reference to several ECHR judgements the Cabinet of Ministers indicates that the above mentioned article protects a person's right to life and defines the responsibility of member countries to refrain from actions, which might deprive a life and to carry out activities to protect a person's life (see: Nitecki v. Poland, decision of 21 March 2002, Application No. 65653/01; Powell v. the United Kingdom, decision of 4 May 2000, Application No. 45305/99; L.C.B. v. the United Kingdom, judgment of 9 June 1998, Reports of Judgments and Decisions 1998-III; Tarariyeva v.Russia, judgment of 14 December 2006, Application No. 4353/03; Keenan v. the United Kingdom, judgment of 3 April 2001, Application No. 27229/95; Cyprus v. Turkey, judgment of 10 May 2001, Application No. 25781/94; Osman v. the United Kingdom, judgment of 28 October 1998, Reports 1998-VIII; Paul and Audrey Edwards v. the United Kingdom, judgment of 14 March 2002, Application No. 46477/99, ECHR 2002-II; D. v. United Kingdom, judgment of 2 May 1997, Case No. 146/1996/767/964; Pentiacova and Others v. Moldova, decision of 4 January 2005, Application No. 14462/03*)*. The State would violate the aforementioned article if the life of a person would be endangered by prohibiting such person's access to public healthcare services. Danger to health, however, should be understood as a real and immediate danger. The Cabinet of Ministers states that for preventing a real and immediate danger to one's health emergency medical services are operating in Latvia. Based on the experience of ECHR concerning application of Article 2 of the Convention, no State obligation emerges to reimburse medicaments for the upkeep of life support.

Therefore, the impugned regulations do not violate the right to life guaranteed under Article 93 of the Constitution.

5.2 The Cabinet of Ministers deems the statement that many countries are fully covering costs of Gaucher's disease treatment is not true. For instance, in the letter of 21 May 2008 from the Ministry of Health of the Republic of Poland it is stated that Poland reimburses full costs of medicament *Imiglucerase (Cerezyme)*. It is, however, indicated that in 2006 the National Health Fund has paid 30886.79 Polish Zlotys (approximately LVL 4 900). This is two times less than the HCISA allocated to G.Z.

5.3 With a reference to the Constitutional Court judgment in Case No. 2006-08-01 of 21 February 2007, in the official response letter it is stated that from the UN Convention follows that the State is obligated to promote economic, legal and social protection of children with disabilities. The UN Convention, however, does not establish any particular procedure and scope of that support. From Article 110 of the Constitution emerges that the State obligation is to create and maintain a system, which ensures special economical and social protection of children with disabilities.

The Cabinet of Ministers states that the impugned regulations restrict rights guaranteed under Article 110 of the Constitution, because it does not define full reimbursement of medicaments for children with disabilities. Considering such restriction it should be evaluated whether: 1) the restriction is established by law; 2) the restriction has a legitimate cause and 3) the restriction correspond to principles of proportionality.

The official response letter states that the impugned regulations comply with the three above mentioned principles. The State would be violating Article 111 of the Constitution if the State's budget would not allow providing minimum health care services for all citizens and the State, in that case, wouldn't define different regulations for reimbursable medication with or without proven therapeutic and economic efficiency.

5.4 The Cabinet of Ministers informs that on 20 November 2008 the European Commission submitted a proposal to the European Council Project for Rare Diseases National Plans Developments. The project states that rare diseases are a threat to the health and life of European citizens since they are not common and very difficult to treat. In the above mentioned project it is advised to EU members to carry out several activities and, also, create plans at national levels.

5.5 The Cabinet of Ministers indicates to the amendments adopted by the *Saeima* on the State Budget of 2009, which state that LVL 727 400 are allocated to the subprogram Medical Treatment of Children (subprogram code 33.12.00; classification code 07620). The Cabinet of Ministers, also, explains that within this subprogram children diagnosed with rare diseases will be provided with the required medication (12 persons). The treatment costs of Gaucher's disease are also included. The above mentioned funding will provide full reimbursement of medicament costs. This funding is allocated to the Children Clinical University Hospital, where patients will receive the medicaments.

The Cabinet of Ministers emphasizes that there also exist treatment programs in hospitals besides the process of compensating purchase costs of the medication as established in the Regulations No. 899. Those programmes are financed by the State and hospitals apply that funding to patients, who need it the most. Therefore children with rare diseases are provided with the funding. Furthermore, in other countries such funding scheme is applied, for covering treatment costs of Gaucher's disease, for example, in Estonia, Denmark and France.

In the response letter is established that taking into account current social and economic situation the State has made the maximum effort to protect patients and to attain a balance between interests of society and interests of individual patients.

6. The invited person – the Ombudsman of the Republic of Latvia (hereinafter – the Ombudsman) – indicates that the content of basic guaranteed rights under Article 93 of the Constitution can be clarified within the contextual interpretation of international treaties, which establish a person's right to life and are binding to the Republic of Latvia, including interpretation of Article 2 of the Convention.

With a reference to various EHCR judgments the Ombudsman indicates that the first sentence of Article 2 of the Convention not only defines the State's obligation to refrain from deliberate and unlawful deprivation of life, but also to carry out activities to protect its citizen life's. The State's actions or inactions in health care area can lead to a violation of Article 2 of the Convention. EHCR, however, does not acknowledge violation of the right to life if the State within its limits has carried out a positive activity for implementing these regulations. Wherewith the determinant factor is whether the State's work in the area of protection of life was or was not carried out. If the State has not carried out all activities within its limits then it shall be considered to be a violation of Article 93 of the Constitution.

The Ombudsman states that the right to health cannot be applicable under common practices. It might be restricted by circumstances defined in the Second Part of Article 2 of the Convention.

The State's obligations are consequent to the right to health protection. Therefore, the aforementioned obligations, including providing the right to life, should be considered in connection with the protection of the right to health. The interests of society, however, should be taken into account.

The Ombudsman indicates that a positive responsibility of the State is carrying out activities to attain the highest standard of health. This obligation includes provision of access to medicaments, which undoubtedly is dependent on the State's budget. Some restrictions may be applied regarding restrictions of particular persons' rights. Such restrictions, however, must be adopted by a democratic procedure.

The Ombudsman states that there is no doubt about the therapeutic efficiency of *Imiglucerase (Cerezyme)*, though that medicament is not included in the Register due to its high price. For this reason, for G.Z. only 12% of the medicament purchase costs are covered. Other patients with life-threatening diseases, however, receive full reimbursement of their medicament bills. Even if the State would allocate extra funding for compensating purchase costs of the medication, the impugned regulations would prohibit the reimbursement of amounts larger than LVL 10 000 for a 12 month period.

Considering the above mentioned facts and arguments and analyzing total funding for health care system, the Ombudsman concluded that the State has not carried out all the necessary work to protect a person's life. The impugned regulations, therefore, are not compliant with Article 93 of the Constitution.

With a reference to the First Part of Article 3 of the UN Convention the Ombudsman agreed with the Senate's opinion that Article 110 of the Constitution establishes higher requirements for the Legislature (to establish such legal regulation that would take into account the age of a patient, whose life is dependent on the required medication). Article 110 of the Constitution is violated by adopting an equal procedure to all individual patients for compensating purchase costs of medication.

7. Pursuant to the Law on the State's Budget of 2009 a new subprogram Rare Disease Medical Treatment for Children was created (code 33.12.00; classification code: 07.620; funding is LVL 727 400). Considering the above mentioned, the Chief Justice asked the Senate to express its opinion about whether after adopting that Law it is still required to clarify its conformity with Articles 93 and 110 of the Convention of the impugned regulations in the particular case.

In the Senate's letter of 17 July 2009 is stated that the creation of the above mentioned subprogram does not resolve this dispute. The impugned regulations are valid and applicable to the hearing of this particular case.

The Senate indicates that a dispute exists; because the impugned regulations apply to patients who are not only children, but the new subprogram only applies to children.

The Senate highlights that the aforementioned Law on the State's Budget is valid only in 2009.

8. Annex 4 of the Law on the State's Budget of 2010 establishes the amount of funding for Rare Disease Medical Treatment for Children subprogram (LVL 727 400).

Considerations:

9. Since amendments to the Law on the State's budget have come into effect, G.Z. was able to apply to the Rare Disease Medical Treatment for Children subprogram. The Regulations No. 899 does not refer to this subprogram. The Constitutional Court, therefore, will review whether legal proceedings should be continued on this matter.

The Senate sought a judicial review in this case. The Constitutional Court states that application of court cannot be unrelated to the case and court shall establish that particular regulations are required in order to hear the case (see Clause 8 of the Constitutional Court judgment in Case No. 2008-10-01 of September 2008 on termination of legal proceedings).

9.1 The Constitutional Court states that the Senate's arguments on the existence of a dispute are unfounded. To rule in the particular case that the Senate does not require assurance whether the impugned regulation complies with the Constitution regarding adult patients.

9.3 It is undeniable that the Law on the State budget is valid only for the particular year. The Constitutional Court, therefore, does not agree with the Senate that the subprogram legitimizes temporary reimbursement (see the Supreme Court

letter No. 10-6/1-1781 of 22 July 2009, pages 3 and 4 of volume 2 of the case file). The subprogram funding exceeds the planned sum of money for treatment of a child for whom such temporary reimbursement is established. Besides, the subprogram is also implemented in 2010.

9.3 It is an obligation of the Administrative Court to decide whether the impugned regulation is relevant or not to the case if the judicial procedure has been altered.

The Constitutional Court established that it is the Senate's responsibility to decide upon regulations required for hearing particular cases. The Senate indicated that amendments to the State's budget of 2009 are not applicable to claimed reimbursement for the period of treatment beginning from 17 December 2007 till 16 December 2008 due the fact that the particular subprogram did not exist at the time.

Hereby it is required to continue the legal proceedings in this matter.

10. Section 19^1 of the Constitutional Court Law defines requirements for submitting an application by a court. The court, on adjudicating a civil matter or a criminal matter in the first instance, according to the appellate or cassation procedures considers that the norm that should be applied in this matter does not comply with the norm (act) of a higher legal force. Except for matters which require widening of such requirements under common judiciary principles or principles of the Constitutional Court procedures (see paragraph 17 of the Constitutional Court judgment in Case No. 2007-23-01 of 3 April 2008).

The Constitutional Court will consider compliance with the Constitution of the impugned regulations within the particular matter as far as it concerns medicaments required for treating children with rare diseases.

11. According to Clause 4 of Paragraph 5 of Section 20 of the Constitutional Court Law the Constitutional Court may decline to hear a matter if that matter

has already been adjudicated. Clause 5 of Section 29 of the Constitutional Court Law establishes that legal proceedings may be terminated if a verdict has been announced about the same claim in a different case. Although, in Case No. 2008-37-03 the constitutionality of the matter was reviewed, the claim (defined in the particular case) was not adjudicated:

1) Clauses 92 and 94 of the Regulations No. 899 were not included in the Claimant application in Case No. 2008-37-03;

2) Claim regarding compliance with Article 93 of the Constitution of Clause 100 and 100^1 of the Regulations No. 899 was not included in Case No. 2008-37-03. It was reviewed, however, while compiling this judgment. Such analysis shall not be considered as adjudicated;

3) Claim regarding compliance with Article 110 of the Constitution of Clause 100 and 100^1 of the Regulations No. 899 was not included in Case No. 2008-37-03.

12. As the Constitutional Court has already analyzed schemes on the procedures of compensating purchase costs of the medication and medical equipment for out-patient treatment, it is not required to analyze again the above mentioned schemes (see paragraph 8 of the Constitutional Court judgment in Case No. 2008-37-03 of 29 December 2008 on).

Whose medicaments are reimbursed which are included in the Medication Register of the Republic of Latvia and comply with diagnoses defined in Annex 1 of the Regulations No. 899. Purchase costs are reimbursed based on the type and severity of disease. There exist 100%, 75% and 50 % covers of medication costs in accordance with Clause 4.1 of the Regulations No. 899. Gaucher's disease and *Imiglucerase (Cerezyme)* medicament are not included in this list.

For individuals the pharmaceutical company covers purchase costs within the allocated State budget in two situations, if the particular medicament is not

included in the Medication Register or without the drug it is not possible to save a person's life. In such cases purchase costs will be covered fully but for not more than LVL 10 000 for a 12 month period. If the purchase costs of medicament exceed the limit, then the rest of the money is to be covered by the patient.

13. Parties involved in the case, questioned not only compliance with Articles 93 and 110 of the Constitution of the impugned the regulations, but also analyzed these regulations with respect to Article 111 of the Constitution indicating that it also considers the right to life, children rights and the right to health.

Articles 93, 110 and 111 of the Constitution state:

"93. The right to life of everyone shall be protected by law.

110. The State shall protect and support marriage – a union between a man and a woman, the family, the rights of parents and rights of the child. The State shall provide special support to disabled children, children left without parental care or who have suffered from violence.

111. The State shall protect human health and guarantee a basic level of medical assistance for everyone."

Parties involved in the Case agreed with Constitutional Court statements that guaranteed rights under the Constitution should be interpreted within international obligations on human rights binding to the Republic of Latvia. It serves as an interpreting tool to establish basic rights and enunciate the state's legal principles and norms (see paragraph 5 of the conclusions of the Constitutional Court judgment in Case No. 2004-18-0106 of 13 May 2005 and paragraph 11 of the Constitutional Court judgement in Case No. 2007-03-01 of 18 October 2007).

In order to evaluate compliance with the interrelated regulations of the impugned regulations, the Constitutional Court will clarify:

1) The content of the right to life guaranteed under the Constitution and interpreting it in connection with international regulations binding to Latvia;

2) How basic rights guaranteed under Articles 93 and 110 of the Constitution could be delimited;

3) Whether Article 93 of the Constitution defines rights broader than international obligations in human rights;

4) Whether the impugned regulations are related to basic guaranteed rights under Article 93 of the Constitution;

5) Children's rights guaranteed under Article 110 of the Constitution and interpreting consequent obligations of the State in connection with international regulations binding on Latvia;

6) Children's rights guaranteed under Article 110 of the Constitution and interpreting consequent obligations of the State in connection with Article 111 of the Constitution;

7) Whether the impugned regulations are in compliance with Article 111 of the Constitution and how such compliance should be reviewed;

8) Whether the impugned regulations comply with the obligation established in Article 110 of the Constitution.

14. No dispute exists regarding right to life being one of the highest values of human rights. It is considered to be a very significant right in the Convention (for instance, Case McCann and Others v. the United Kingdom, judgment of 27 September 1995, Series A, No. 324, Paragraph 147; Calvelli and Ciglio v. Italy [GC], judgment of 17 January 2002, Application No. 32967/96, ECHR 2002, Paragraph 48). This right is established as inalienable. The

Constitutional Court agrees with the Senate that the right to life recognizes the physical existence of a person and is a precondition for mental health and actions or behaviour of a person. The right to life forms the premise for implementing the basic rights of people

The right of life is defined in several important international regulations, which are binding on Latvia. Among them is also the Convention. Article 2 of the Convention establishes:

"Article 1 – Obligation to respect human rights

The High Contracting Parties shall secure to everyone within their jurisdiction the rights and freedoms defined in Section I of this Convention.

Article 2 – Right to life

1 Everyone's right to life shall be protected by law. No one shall be deprived of his/her life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.

2 Deprivation of life shall not be regarded as inflicted in contravention of this article when it results from the use of force which is no more than absolutely necessary:

a in defence of any person from unlawful violence;

b in order to effect a lawful arrest or to prevent the escape of a person lawfully detained;

c in action lawfully taken for the purpose of quelling a riot or insurrection."

14.1. Article 2 of the Convention protects a person from such violations of life carried out by the State to deprive life (irrespective of being intentional or unintentional). In the particular case, however, a dispute does not exist

whether the context of the above mentioned article should be evaluated within this case. The impugned regulations do not regulate any actions that might be intended to deprive a person's life, including G.Z.

14.2. Article 2 of the Convention is established as an obligation on the State to protect a person's life. The State shall protect a person from actions carried out by it or another person. To realize this obligation the State has only a certain freedom of action. Efficient protection of life is required; however, the type of tools applied and the severity of action depend on a particular situation. Countries have agreed that the most important tool to protect life is the prohibition on depriving a person's life. This State obligation includes not only issuing related regulations, but also creating an efficient system for monitoring implementation of those regulations (see Grabenwarter C. Europäische Menschenrechtskonvention. München: C. H. Beck, 2005, pages 130-131).

ECtHR has concluded that Article 2 of the Constitution defines the State's obligation to protect within its jurisdiction living persons from other persons criminal actions (see ECHR judgment of 14 March 2002 in Case Paul and Audrey Edwards v. the United Kingdom, Application No. 46477/99, *ECHR 2002-II*, Paragraph 54).

With reference to the above mentioned State's obligation, the ECtHR states that: "It is possible that actions or inactions of State's institutions in the field of healthcare policy in certain conditions may cause a responsibility relating to Article 2 of the Convention" (see Case Powell v. the United Kingdom, decision of 4 May 2000, Application No. 45305/99). This statement has been cited in several ECtHR judgments to which involved parties refer to in this case. It should be taken into account that the above mentioned case concerned the issue whether a doctor should be accused for the death of a ten year old child. Furthermore, the court did not review the case in this particular instance.

The ECtHR mainly relates the statement to systematic and structural obligations, for instance, establishing requirements for hospitals, scheme of rights protection for investigating cases connected with death of patient (see

ECtHR judgment of 4 January 2008 in Case John Shelley v. United Kingdom, Application No. 9310/81).

The impugned regulations do not restrict or undermine activities carried out by the State to define criminal and civil liability for depriving another person's life, including the death of a patient, which might be caused by a physician, unintentionally or intentionally. The impugned regulations do not apply to work of institutions responsible for monitoring healthcare system.

G.Z. is not a victim of physician negligence. According to diagnostic decision of the Medical Genetics doctors' council he/she has a hereditary genetic pathology. The case file does not contain any materials which could indicate that the State could implement actions to prevent people from contracting the particular illness.

14.3. A disputable question is if and how widely Article 2 of the Convention defines State's obligations to protect life if a life is endangered by external factors such as illness or impact of environment. The history of creating the Convention suggests that the provision on social rights was not a part of it. Therefore, the State's obligation to implement actions regarding Article 2 of the Convention exists only if a life endangerment is immediate and specific (see Grabenwarter C., page 133).

14.3.1. In the Claimant's application it is stated that the impugned regulations should be considered as an immediate and specific endangerment of life within interpretation of Article 2 of the Constitution. The Senate states that G.Z. will die if he/she does not receive the required medication. In the administrative case a dispute whether G.Z. requires medication for life-support within interpretation of the Regulations No. 899 does not exist.

A difference, however, exists between the interpretation of "life-support" in Regulation No. 899 and the interpretation of "immediate and specific endangerment of life" in Article 2 of the Convention. Such regulations do not exist, which establish specific lifespan for a person. The State has no

obligation to ensure maximum lifespan. No country in the world is able to implement that.

Lifespan of a person depends on several factors (e.g. environment, food, eating habits, sleep, and stress level). It should be considered that not every action, which influences lifespan, might be related to the right to life.

Emergency medical services activities are under Regulations on emergency medical care, but not under the Regulations No. 899 in the event of immediate and specific endangerment of life. The obligations of the Cabinet of Ministers do not emerge from the Pharmaceutical Law, but from the Medical Treatment Law.

The aim of the Medical Treatment Law is to provide qualitative prevention, rehabilitation and treatment of trauma. Section 16 of that Law establishes that everybody has the right to receive emergency medical care in accordance with procedures prescribed by the Cabinet of Ministers. Emergency medical care is free of charge.

Clause 3.4 of the Cabinet of Ministers Regulations No. 92 of 30 January 2009 defines that the emergency service obligation is: "to provide and manage emergency medical care in emergency situations, as well as when a medical institution cannot provide the required services in particular situations anymore". The impugned regulations do not regulate reimbursement of medication purchase costs. They, however, regulate reimbursement of medication purchase costs for out-patient treatment, which by its definition is not related with immediate and sudden death of a person.

Moreover, Regulation No. 899 regulates only one of the cases, when a person, who does not need emergency medical services yet, receives full or partial reimbursement of medication purchase costs from the State. Other cases regulate the Medical Treatment Law.

14.3.2. In the particular case a sudden and immediate death will occur only if he/she will not receive the required medicament. A slow and progressive development is typical for Gaucher's disease. It may have different levels of severity (see http://www.gaucher.org.uk/gaucher_disease.php?show=en&id=48). At the time when treatment for this disease was not invented, people with this disease reached maturity (see Fragen und Antworten zu Morbus Gaucher http://www.genzyme.de/pdfs/de_tp_cz_patienteninformation.pdf).

It is possible that by the time this disease progress the situation in the pharmaceutical field could change. Already adults have an alternative treatment – medicament *Miglustat.* At least three pharmaceutical projects are creating and developing this medicament. Medicament *Shire* is under registration and medicament *Amicus* is under clinical trials. Also, medicament *Protalix Biotherapeutics (see http://www.ggd-ev.de)* is being created and developed. The above mentioned medicaments after their release in the market might replace medicament *Imiglucerase (Cerezyme)* and probably lower its price. The Cabinet of Ministers indicates that the company *Genzyme* works with a considerable profit. For instance, in 2004 it sold its products for 840 million dollars with 90% profit (see http://www.medicalnewstoday.com/articles/33642.php).

Within the interpretation of Article 2 of the Convention immediate endangerment of life does not exist in this particular case. Without denial it is important to take the required medicament regularly for G.Z.'s health and successful development.

Furthermore, it does not mean that a person cannot purchase the required medicine if the State does not fully cover the purchase costs of that medicament. For instance, the Ministry of Health of the Republic of Lithuania states that the purchasing capacity of only 3 patients with Gaucher's disease is covered by the State and the purchasing capacity of other patients with Gaucher's disease is covered by a pharmaceutical company. (see page 54 of volume 1 of the case file).

The Republic of Latvia has created a legal system which allows persons to seek help from other persons. According to Section 2 of the Public Benefit Organisation Law activities with the purpose of health promotion and illness prevention are acceptable. A person, who donates to public benefit organisations, is authorised to receive tax allowances.

For instance, till July 2009 enterprises which donated money to public benefit organisation, could receive tax allowances established in Section 20 of Law on Enterprise Income Tax. According to that Law tax was reduced by 85% if money was donated to registered organisations and foundations. The tax allowance could be up to 20% of taxable income. Amendments to the Law on Enterprise Income Tax of 24 September 2009 supplemented that Law with Section 20^{1}. Clause 5 of Transitional Provisions defines that tax allowances shall not exceed 20% of total taxable income for taxation period started in 2009.

Although, cooperation with public benefit organisations has its downsides for people asking that help. These difficulties should not be considered as violation of Article 2 of the Convention.

14.3.3. Both the Senate and the Ombudsman indicate two cases when people claimed about violation of right to life due to refusal by the State to cover required medicament purchase costs (see ECtHR judgments in cases: Nitecki v. Poland, decision of 21 March 2002, Application No. 65653/01; Pentiacova and Others v. Moldova, decision of 4 January 2005, Application No. 14462/03).

The Senate states that reimbursement of costs was proportionally larger compared to the particular case.

The Ombudsman emphasizes that according to the ECHR a violation of right to life does not distinguish if the State has carried out all possible actions to implement required regulations. The State's contribution, therefore, is the leading indicator.

The aforementioned statements cannot be simply interpreted while concluding opposite facts (*argumentum e contrario*). The ECtHR arguments in the above mentioned judgments indicate that the statement of reasons in the particular application is unfounded, so the case cannot be heard in the court. Concluding the opposite about the statement of reasons it might be possible that the court would hear the case. Hearing the case, however, does not mean that violation of Article 2 of the Convention would be acknowledged.

The Senate's and the Ombudsman's statements cannot be interpreted in such way, which would mean the violation of the Convention.

According to the case about care of kidney patients in Moldova ECtHR indicates that the basic problem in many cases is lack of public funding for healthcare. To ground their claims, plaintiffs assert that Moldova's funding for healthcare compared to such countries as the USA, the UK, Australia, and Israel. ECtHR does not contest the fact that plaintiffs lack finances to cover their treatment, which is not paid by the State and is very important to fight their illness. The EHtCR, however, emphasized that public funding should be diverted to other important tax payer needs (considering the limited amount of such resources). Although, all people should have equal access to public healthcare due to lack of resources in many countries individual patients cannot receive full healthcare, especially if it is expensive and long-term. According to Article 8 of the Convention, the ECtHR stated that the Constitution does not guarantee the right to free of charge health care as such (see ECtHR judgment in Case Pentiacova and Others v. Moldova, decision of 4 January 2005 on the admissibility of the Application No. 14462/03, ECtHR 2005-I).

Wherewith the impugned regulations do not concern the right to life guaranteed under Article 2 of the Convention.

15. The Constitutional Court will clarify whether Article 93 of the Constitution establishes broader rights than Article 2 of the Convention and Protocol 6.

15.1 The Senate in its applications compares similar interpretation of the Basic Law of Germany to Article 93 of the Constitution. The Senate concludes that Article 93 of the Constitution includes issues regarded to the above mentioned interpretation.

The Senate, however, has not considered in detail the differences between the Basic Law of Germany and the Constitution of Latvia, as well as differences in regulation of compulsory health insurance systems.

Firstly, the Basic Law of Germany establishes Germany as a socialist country, nevertheless, it does not state the right to work, dwelling, education or the right to exist.

Secondly, Section 2 of the Basic Law is stated as the right to life and bodily integrity. Limitations of such rights are derived out of law establishing the rights. Restrictions are not diminished regarding the Convention. They are reviewed using proportionality principles (see Sachs M., page 118). In the Senate's application, moreover, it is stated that the author of the above mentioned statements claims that the right to life emerges from the right to bodily integrity.

The right to life is reviewed in a broader sense in the Basic Law of Germany. In A. Weber's book on legal norms and practice in human rights field there is a chapter "Right to life, bodily and physical integrity". This chapter reviews rights mentioned in the Convention, Protocol 6 and the right to health. By analyzing how the Italian Court interpreted its legislation regarding the right to health, the Senate indicates that the Italian Court applied a broad interpretation of that right and even included issues concerning healthy environment. At the same time the court rejected the fact about limited State budget and required evaluation of that (see Weber A. Menschenrechte, München: Sellier. European Law Publishers, 2004, page 108).

In the database on Constitutional Case-Law of the Venice Commission the right to life and the right to health are structured differently. The right to life

(No. 5.3.2) belongs to civil and political rights, but the right to health (No. 5.4.19) belongs to economic, social and cultural rights (see *http://www.codices.coe.int/NXT/gateway.dll?f=templates&fn=default.htm*).

In situations when constitutional norms are interpreted with the help of EU legislation it should be remembered that Article 111 of the Constitution establishes the right to life and basic medical care. Therefore, these values are already regarded as separate basic rights in contradistinction to EU legislation where these rights are only components of basic rights or human rights.

The Ombudsman also refers to the compliance of the impugned regulation with Article 93 of the Constitution in relation to Article 111 of the Constitution. Moreover, the Senate analyzes the compliance regarding Article 111 of the Constitution.

Thirdly, the Senate refers to the judgment of the Federal Constitutional Court, which states that, the existence of such a legal norm, which is in contradiction to the first sentence of Second Paragraph of Section 2 of the Basic Law, prohibits cover of costs for alternative treatment for children with rare life-threatening incurable disease. In the same paragraph, however, the court has indicated conditions why such statements exist. Therefore, the state takes responsibility for the insured's bodily integrity under legal norms of Germany (see BVerfG, 1 BvR 347/98 of 6.12.2005, paragraph no. 65, http://www.bverfg.de). In the particular judgment the Court of Germany has indicated an important principle of compulsory health insurance system. Persons subjected to this system receive proper medical health apart from the amount paid for insurance. The insured collectively takes responsibility for every individual's health-risks. The Latvian system is different.

15.2 The Constitutional Court states that by reducing the scope of Articles 93 and 111 of the Constitution, rights guaranteed under Article 93 could not be interpreted in a broader sense. The restrictions of those rights should be interpreted in a narrow sense. The Constitutional Court agrees with the Senate

and the Cabinet of Ministers that Article 93 of the Constitution can be restricted on by situations defined in Article 2 of the Convention.

Since the Constitutional Court has already concluded that the impugned regulations are not related to Article 2 of the Convention, the impugned regulations are not applicable to Article 93 of the Constitution. The Constitutional Court, moreover, has previously concluded that the State does not have an obligation to provide required medication for everyone free of charge (see paragraph 12.1.1 of the Constitutional Court judgment in Case No. 2008-37-03 of 29 December 2008). The Constitutional Court also reviewed arguments of the Senate and acknowledged them as unpersuasive.

Hereby the impugned regulations comply with Article 93 of the Constitution.

16. It is unnecessary to review the interpretation of Article 110 within international regulations on children's rights. The Constitutional Court has already concluded:

"The right of children with disability to special care and assistance is guaranteed under the UN Convention of 1989 on the Rights of the Child. Under Paragraph 1 of Article 23 of the Convention, States Parties recognize that a child with mental or physical disability should enjoy a full and decent life in conditions which ensure dignity, promote self-reliance and facilitate the child's active participation in everyday life. Paragraph 2 of the same Article provides that the State should recognize the right of the disabled child to special care. Paragraph 3 provides that in accordance with Paragraph 2 of the present Article, an assistance shall be provided free of charge whenever it is possible, taking into account the financial resources of parents or guardians. It shall be designed to ensure that the disabled child has efficient access to education, training, health care services, rehabilitation services, preparation for employment and recreational opportunities, so that every child could achieve the fullest possible social integration and individual development, including his/her cultural and spiritual development.

The Convention defines that the State is obliged to promote the economic, legal and social protection of a disabled child. However, the Convention does not provide any particular assistance system. Hereby emerges that Article 110 of the Constitution establishes that the State shall be liable to form and maintain the system providing special social and economic protection for disabled children. (see paragraph 10 of the Constitutional Court judgment in Case no. 2006-08-01 of 21 February 2007).

It should be taken into account that Article 4 of the UN Convention states: "States Parties shall undertake all appropriate legislative, administrative, and other measures for the implementation of the rights recognized in the present Convention. With regard to economic, social and cultural rights, States Parties shall undertake such measures to the maximum extent of their available resources and, where needed, within the framework of international cooperation."

The positive responsibilities of the State resulting from Article 110 of the Constitution should not be specified so far that the same Article would define obligation to the State provide all children all required medical services free of charge at any circumstances.

17. In the particular case, Article 110 of the Constitution shall be interpreted within the framework of Article 111 of the Constitution.

With a reference to General Comment No. 14 on the right to the highest attainable standard of health formulated by the Committee on Economic, Social and Cultural Rights, the Constitutional Court has concluded that the right to health is not the same as the right to be healthy. The right to health includes particular freedoms and entitlements. The freedoms include the right to control one's health and body, and the right to be free from interference, such as non-consensual medical treatment. It should be taken into account that the State cannot take full responsibility for a person's options to achieve the highest standard of health due to the impact of genetics, the immunes system's

vulnerability and unhealthy lifestyle. Therefore, the State's obligation is to provide access to services of medical institutions, availability of equipment and medicament and other conditions which have an impact on achieving the highest standard of health. From the right to health emerges the State's obligation to carry out such activities which would protect a person's health (see paragraph 11.2 of the Constitutional Court judgment in Case No. 2008-37-03 of 29 December 2008).

The State, however, has an obligation to provide efficient and equal balance of funding which would allow providing the vast majority of society with basic medical care considering the need of individual patients to receive more expensive treatment (see paragraph 12.1 of the Constitutional Court judgment in Case No. 2008-37-03 of 29 December 2008).

Interpretation of Article 110 of the Constitution within Article 111 of the Constitution shows that the State's obligation to carry out special activities for protecting the health of disabled children, including the provision requiring medical services and medicaments. This, however, does not imply the fact that the State shall provide with medication irrespective of its price.

In this matter, special characteristics of social rights define the judiciary's powers. Implementing social rights the Legislature obtains the freedom of action as far as it is prudently related to economic situation of the State. This implies that the freedom of action is limited (see paragraph 13 and 14 of the Constitutional Court judgment in Case No. 2006-07-01 of 2 November 2006). Furthermore, the judiciary has an obligation to review whether the Legislator has observed the boundary of this freedom of action.

Within its limits the Court should verify whether:

1) The Legislator has carried out activities to provide persons with a chance to apply social rights;

2) These activities are carried out properly;

3) General principles of legislation are observed (see paragraph 8 of the Constitutional Court judgment in Case No. 2007-13-03 of 19 December 2007).

18. In the application the compliance with Articles 91 and 111 of the Constitution is not claimed. The Constitutional Court, however, should ascertain whether the claim should be broadened to verify conformity with the Constitution of the impugned regulations. The Ombudsman, furthermore, reviews the impugned regulations regarding Article 111 of the Constitution.

As it was mentioned above the Constitutional Court has already reviewed compliance with Article 91 and 111 of the Constitution of two impugned regulations.

Moreover, the Senate in its application has included critical arguments regarding the Constitutional Court's statements produced in this judgment. The Senate also stated that the particular matter makes to review differently the proportionality of basic right restriction.

The above mentioned Senate's opinion is unfounded. The facts of the particular case were already familiar to the Constitutional Court while hearing Case No. 2008-37-03 (see paragraph 3 of this judgment).

Wherewith it is not required to review issues concerned the compliance with Articles 91 and 111 of the Constitution of the impugned regulations.

19. The Senate contests the words mentioned in the second sentence of Clause 92, "within the granted limits of medication purchase". To find out the compliance of those words, Article 66 of the Constitution should be taken into account. The Constitution establishes that the *Saeima* annually decides on the State budget. The State budget is a financial plan based on present legislation which defines the State's income and expenses for a particular period of time – the financial year.

The Constitutional Court has concluded: "in the State budget finances are defined to implement the State's obligations, which are covered by the State income, in a certain period of time. All governmental institutions are affiliated to the State budget. In a particular financial year only a defined sum of money can be used for established purposes" (see paragraph 1 of the Constitutional Court judgment conclusions in Case No. 1998-01-05(98) of 27 November 1998).

Therefore, if the impugned words would not be in the second sentence of Clause 92 of the Regulations No.899, then HCISA, according to Article 66 of the Constitution, may not allocate more funding for medicament reimbursement than established in the State budget.

20. The Constitutional Court agrees with the Senate that Article 110 of the Constitution defines a special obligation to the State to help disabled children. This norm establishes such judicial procedure which would take into account the age of patient whose life depends on required medication. Article 110 of the Constitution defines obligation to the *Saeima* to decide on allocating funding to this cause.

Whether the State has carried out that obligation cannot be evaluated reviewing the impugned regulations irrespective of legal norms and acts regulating pharmacy and medicine.

20.1 The impugned regulations are included in the regulations of the Cabinet of Ministers. The Cabinet of Ministers of the Republic of Latvia can issue normative acts only if the Legislator has specifically defined in Law such delegations. Based on that delegation the Cabinet of Ministers issues normative acts which results from the implementation of legislation. Those normative acts are created from procedural norms. In particular cases a normative act can be created from material norms, but it shall be adopted by special authorization by the Legislator's (see paragraph 16 of the Constitutional Court judgment in Case No. 2007-04-03 of 7 October 2007).

The Regulations No. 899 is issued according to Section 5 of the Pharmaceutical Law. That Section authorizes the Cabinet of Ministers to define reimbursement procedures only for medicaments required by out-patient treatment.

The word "procedure" in Section 5 of Pharmaceutical Law indicates to normative acts with procedural characteristic. For such regulations material procedures cannot be included (see paragraph 20 of the Constitutional Court judgment in Case No.2007-04-03 of 7 October 2007).

The obligation of the Cabinet of Ministers is to create such a procedure which would establish equal and proportionate division of allocated budget within the framework of the Constitution and the legislation. The Cabinet of Ministers cannot create such procedure which would exceed the allocated amount of budget.

20.2 The Senate's opinion that conformity with the Constitution of the impugned regulations should be reviewed regarding the allocated and the total budget is unfounded. The Ombudsman's opinion that within the particular case the compliance with the Constitution of the impugned regulations should be reviewed considering the total amount of allocated budget to the field of healthcare is also unfounded.

If the Constitutional Court concluded that the impugned regulations are not compliant with the Constitution and declared invalid, then the Cabinet of Ministers still could not establish reimbursement procedures other than those defined by the *Saeima* in the Law on the State budget.

20.3 The aim of the Pharmaceutical Law is to regulate the work of natural and legal persons in the field of pharmacy and to ensure manufacturing and distributing of qualitative, medically suitable medicaments with a preventive effect and diagnostic level. The Pharmaceutical Law does not regulate how and what medically treats persons and does not establish that a patient has a right to receive medicaments which are paid for by the State.

The aim of the Medical Treatment Law is to ensure qualitative medical services. Section 9.1 of that Law defines medical treatment as being carried out according to clinical guides or methods used and an evaluation of medicament as the effectiveness of the medical treatment, which is performed according to proven medical principles. The Cabinet of Ministers creates a procedure by which clinical guides are created, registered and implemented.

According to Section 4 of the Medical Treatment Law the Cabinet of Ministers shall determine: "The procedures for the organisation and financing of health care, procedures for the establishment of queues of applicants for receipt of systematic health care services, the types and amounts of medical treatment services thereof, which are paid for from the State basic budget and from the resources of recipients of services, as well as the procedures for such payments shall be determined by the Cabinet." Conforming to Section 4 of the Medical Treatment Law the Cabinet of Ministers adopted Regulations No. 1046 of 19 December 2006 on Procedures for Health Care Organisation and Financing (hereinafter – the Regulations No 1046).

According to Paragraph 2 of those Regulations the allocated budget for healthcare is used for covering emergency medical services, primary and secondary healthcare services and purchase costs of reimbursable medicaments and medical equipment, centralized purchases regarding normative acts defining procedures of compensating purchase costs of the medication and medical equipment for out-patient treatment.

Conforming to Paragraph 3 of those Regulations the State Health Centre responsibility is to plan the financing for not less than 32% of out-patient treatment, but for covering in-patient treatment of not more than 60.6% of the allocated budget.

The vast majority of the allocated State budget is used for in-patient treatment. The impugned regulations do not regulate those medical services. In receiving in-patient treatment a patient pays patient duty; however, medical institutions

may also collect patient co-payment. According to the Paragraph 10.1 of the Regulations No. 1046 children up to age 18 are free from paying such duties.

Paragraph 3 of those Regulations establishes that while signing an agreement between a medical institution and the State Health Centre, a clause defining priority obligation to provide medical care for children and pregnant women must be included.

To provide special care for children the State founded the University Children's Hospital. According to Clause 130.2.1.3 of the Regulations No. 1046 the University Children's Hospital receives the funding prior to other medical institutions.

Detailed evaluation of the Regulations No. 1046 for every statement is not required in the particular case. From the aforementioned, however, it can be concluded that the State has not avoided its obligations defined under Article 111 of the Constitution. The impugned regulations are irrespective of those activities intended for establishing additional positive preconditions in the field of child healthcare.

20.4 The Cabinet of Ministers, in the official response letter, indicates that during the process of creating a reimbursement procedure of medicaments it is taken into account that full medical out-patient treatment allows to prevent deterioration of the patient's health and hospitalization. Irrespective of the reimbursement procedure, medicaments during the period of out-patient treatment are covered and this procedure relates not only to therapeutic efficiency, but also to economic efficiency connected to lifespan ratio. The Legislator, not the Cabinet of Ministers defines how much the State might pay for one year of life.

The impugned regulation does not include an absolute prohibition on the State authorities to reimburse more than LVL 10 000 for one year. It includes restrictions to implement such reimbursement in a particular procedure. It is required to divide again the allocated budget to reimburse such medication

which does not ensure required lifespan ratio. In such case the Legislator's approval is required. The *Saeima*, however, shall take responsibility for deciding whether the required medicament will be covered for a person and from which budget will it be implemented.

The impugned regulation, furthermore, applies only to one procedure which is covered by the State. This regulation does not regard in-patient treatment and medicament centralized purchase procedure. The Cabinet of Ministers indicates that existing State financed subprograms are being carried out by hospitals. At present the treatment program for children with rare diseases is implemented by medical institutions, but not according to the procedure defined in the Regulations No. 899.

From the case file materials it is inferred that in other countries, for instance, in Denmark and Spain, patients receive required medicament in hospitals (see pages 56-57 and 62-64 of volume 1 of the case file).

The Cabinet of Ministers states that reimbursement procedure through medical institution is required due to the fact that medicaments for out-patient treatment are prescribed according to their descriptions. It is disproportionate to provide expensive medicament reimbursement for out-patient treatment without medical professional assistance and evaluation, which if needed would differentiate between medicament doses and use them appropriately within the allocated funding. For example, in Israel over a period of 10 years an experience has been gained for treating Gaucher's disease and defining individual doses depending on the severity of illness. In this way maximum effect has been achieved with minimal doses (see Kesselman I., Elstein D., Israeli A., Chertkoff R., Zimran A., National health budgets for expensive orphan drugs: Gaucher disease in Israel as a model, http://www.ncbi.nlm.nih.gov/pubmed/16824774).

The evaluation of therapeutic and economic efficiency is the key factor of the reimbursement procedures established in Regulations No. 899. Within the overall reimbursement procedure that evaluation is carried out while

registering medicaments in the Medication Register. Within the individual reimbursement procedure the maximum amount that HCISA can cover for one patient is LVL 10 000 for a 12 month period.

The Cabinet of Ministers shall establish such monitoring procedures which prevent inexpedient usage of the State budget in case of adopting such reimbursement amount that exceed the defined sum of money and if the therapeutic and economic efficiency has not been evaluated. A separate procedure, therefore, is still required. In the particular case the medicament is provided within the framework of a subprogram, which simultaneously monitors the effectiveness of using this medicament.

20.5 It should be taken into account that rare diseases are considered to be an issue in many countries (in EU rare diseases are defined as diseases afflicting not more than five people of ten thousand suffer from). It is considered that pharmaceutical companies, due to the small market and large manufacturing costs would not be interested in manufacturing medicaments for rare-disease treatments if they did not have a judicial status (orphan drug, orphan pharmaceutical drug, orphan medicinal product, Orphan-Arzneimittel, Arzneimittel für seltene Leiden). Medicaments for treating rare diseases after registration are subordinated to specific judiciary regulations, which establish competition limitations (Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ 2000 L 18, p. 1)). Such regulations may promote inventing that kind of medication and may also allow the manufacturer to set prices due to the lack of competition in the market.

Rare diseases are acknowledged as a problem in all EU member countries. In the Commission report it is indicated that there exists no other actions and methods in the 27 EU member countries in the healthcare field which are considered as inefficient and unsuccessful as rare diseases are. The small number of patients with this disease and the requirement to mobilize resources encourage acting at the European level regarding Article 152 of the Treaty establishing European Community. There are no options to create a centre for

treating rare disease in every member country due to the high costs of such centre. The specific knowledge should "travel around" and not patients. Patients, although, should have a chance to visit such centres if needed. Current EU legislation is not properly adjusted to resolving issues concerning rare diseases (see *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2713:FIN:LV:DOC*).
At this point member countries only start to realize issues concerning rare diseases, Latvia should not be admonished for not creating programs for rare disease treatment.

If a child has a rare disease and it is not possible to reimburse costs of the medicament, Article 110 defines the obligation of the Cabinet of Ministers and the *Saeima* to review particular situation. That Article, however, does not establish an obligation to fully reimburse medicament purchase costs under the procedure defined in the impugned regulations.

The impugned regulations, as a part of the Pharmaceutical Law and the Medical Treatment Law, are not in contradiction with positive obligations of the State defined by Article 110 of the Constitution. The impugned regulations, therefore, are in compliance with Article 110 of the Constitution.

21. Regulations No. 899 and 1046 does not state that a person can ask for creating programs for the treatment of children with rare diseases funded by the State. Also, the HCISA in its resolution did not indicate towards covering those costs in an alternative way. This, however, cannot restrict a person from approaching the Ministry of Health on this matter with a request to review that situation regarding Article 110 of the Constitution.

For more than one year competent authorities were not informed about G.Z.'s diagnosis and required medicament until a proposal to create a particular subprogram was heard in the *Saeima*.

The evaluation whether action of State authorities in this particular case was in compliance with the principles of the Constitution depends upon specific circumstances of the case, for example, possible irreversibility and severity of the after-effects of the illness, alternative funding options and other circumstances. The evaluation of circumstances could not have an impact on the regulation's compliance with the Constitution.

Adjudication:

Based on Sections 30 – 32 of the Constitutional Court law, the Constitutional Court rules:

Article 93 and 110 of the Constitution of the Republic of Latvia comply with the Clause 92 second sentence's words "within the granted limits of medication purchase", Clause 94's words "with the exception of mentioned case in the Regulation Paragraph 100¹", Clause 100's words "not more than the amount of LVL 10 000 for one patient in 12 months " and the second sentence of Clause 100¹ of the Cabinet of Ministers Regulations No. 899 of 31 October 2006 on the procedures for compensating purchase costs of the medication and medical equipment for out-patient treatment.

The judgment is final and not subject to appeal.

The judgment comes into effect on the day it is published.

The Chief Justice G. Kūtris