THE CONSTITUTIONAL COURT
OF THE REPUBLIC OF LATVIA

JUDGMENT
ON BEHALF OF THE REPUBLIC OF LATVIA
Riga, 29 December 2008
in Case No. 2008-37-03

The Constitutional Court of the Republic of Latvia, composed of the Chairman of the Court session Gunārs Kutris, Justices Kaspars Balodis, Aija Branta, Juris Jelāgins, Kristīne Krūma and Viktors Skudra,

based on Article 85 of the Satversme (Constitution) of the Republic of Latvia and Article 16 (3), the first part of Article 17 (9), Article 19.[1] and Article 28.[1] of the Constitutional Court Law,

having regard to the constitutional claim of the Administrative Regional Court,

on 2 December 2008 in a Court session examined the case in written proceedings:

„On Compliance of Section 100 and Section 100.1 of the 31 October 2006 Cabinet Regulations No. 899 "Procedures for the Reimbursement of Expenses toward the Purchase of Medical Products and Medical Devices for the Out-Patient Care" with Article 91 of the Satversme (Constitution) of the Republic of Latvia"

The Constitutional Court has established:

1. On 31 October 2006, the Cabinet of Ministers adopted the Regulation No. 899 "Procedures for the Reimbursement of Expenses toward the Purchase of Medical Products and Medical Devices for the Out-Patient Care" (hereinafter – the

Regulation No. 899). Section 100 and Section100.[1] thereof (hereinafter – the Contested Norms) provide the following:

"100. The State Mandatory Health Insurance Agency shall reimburse the expenses toward purchase of medicinal products and medical devices in the cases referred to in this Chapter in the amount of maximum 10000 lats per one patient within the time period of 12 months.

100.[1] If the foreseen expenses exceed the expenses referred to in Section 100 of these Regulations, the State Mandatory Health Insurance Agency shall specify the reimbursement expenses for one package of the medicinal product in Decision on the reimbursement of medicinal products. The difference between the price of one package of the medicinal product and the reimbursement amount specified in Decision of the Mandatory Health Insurance Agency shall be covered by the patient upon receipt of the medicinal product in the pharmacy."

2. The applicant – the Administrative Regional Court (hereinafter – the Applicant) asks to recognize the Contested Norms as non-compliant with Article 91 of the Satversme (Constitution) of the Republic of Latvia (hereinafter - the Satversme).

The Applicant, when examining an application of Irina Salova regarding the temporary regulations, has recognized that circumstances of the case imply violation of the principle of legal equality regarding I. Salova. If the fundamental principles included in the Regulation No. 899 are not observed, Article 91 of the Satversme is being breached.

The Applicant indicates that Z 94.8 was diagnosed to I. Salova. This disease can be treated with *Glivec* medication to ensure her vital functions. According to the Decision of 23 March 2007 of the State Mandatory Health Insurance Agency No. 9/1.1-10/1987, expenses towards purchase of these medical products was reimbursed to I. Salova at the amount of 100 percent because this medical product has been included into the list of reimbursable medical products.

Since the organism of I. Silova has elaborated resistance against *Glivec* medical product, she has been assigned a 12 month therapy using *Sprycel* medical product according to a decision of doctors because this is the only

medical products that can prevent recrudescence of the disease. Since *Sprycel* medical product has not been included into the list of reimbursable medical products, reimbursement of purchase thereof is limited to 10 000 lats per 12 months.

The Applicant holds that I. Salova enjoys equal and comparable conditions if compared to those persons for whom an identical disease has been diagnosed and who receive compensation, at the amount of 100 percent, for the purchase of the medical products necessary for ensuring their vital functions, namely *Glivec* medical products.

The Contested Norms provide for a different attitude because, in the result of application thereof, the persons for whom one and the same disease has been diagnosed and who need such medical products that would ensure their vital functions are provided for different amount regarding reimbursement of the purchase of medical products.

According to the Applicant, by providing for a limited reimbursement of the purchase of medical products, I. Salova is, in fact, deprived of *Sprycel* medical products necessary for her. Namely, the difference of the price of the medical products and reimbursement amount that she has to cover herself constitutes 2707.09 lats per month, i.e. 78 percent of the total price of the medical products. Consequently, I. Salova is not able to purchase this medical product and thus cannot use the lawful compensation.

The Applicant holds that there is no legitimate objective for providing for a different attitude because the regulation included in the Contested Norms, in fact, is more advantageous for those persons for whom a disease identical to that of I. Salova has been diagnosed but medical products necessary for treating thereof are included into the list of reimbursable medical products. When providing for the order, according to which the amount of reimbursement for each separate person shall be established, it is necessary to take into consideration the basic principles of reimbursement of the purchase of medical products as provided for in the Regulation No. 899, namely, if a patient has been diagnosed with a chronic, life-threatening disease or a disease that results in a severe, irreversible disability and the treatment of the disease requires the use of

the respective medical products to maintain the patient's vital functions, the reimbursement for the purchase of medical products shall be established at the amount of 100 percent.

The fact that *Sprycel* are not included into the list of reimbursable medical products and therapeutic and costs efficiency has not been examined is a formal criterion that does not depend on the will of I. Salova. Moreover, non-inclusion of particular medical products into the list does not imply that their efficiency has not been proved. Such conclusion can only be made after assessment of the medical product rather than guiding oneself by a forma criterion of medical products being or not included into the list of reimbursable medical products.

If it would be included into the fundamental principles of the Regulation No. 899 that only such medical products, the costs of which does not exceed a particular sum, for instance, 10 000 lats per one patient for the period of 12 months, would be included into the list of reimbursable medical products, the principle of equality would also be observed in relation to those persons who has been diagnosed with a disease that requires using such medical products that would ensure their vital functions.

The Applicant assumes that the procedure for establishing the amount for reimbursement of the purchase of medical products may contain preconditions that restrict the rights of persons to apply for reimbursement of the purchase of medical products at the amount of 100 percent. The Cabinet of Ministers, however, by adopting a respective normative enactment, should guide itself not only by the laws regulating the State budget, but also the norms included into the Satversme. It should be assessed in particular whether the restriction of the rights complies with the legitimate objectives provided for in Article 116 of the Satversme, as well as the principle of justice, equality and proportionality should be observed.

3. The institution that passed the contested act – **the Cabinet of Ministers** – does not agree with the opinion of the Administrative Regional Court and holds that the Contested Norms do comply with Article 91 of the Satversme.

The Cabinet of Ministers holds that, when assessing compliance of the Contested Norms with the Satversme, it is necessary to take into consideration Article 111 of the Satversme which provide that the State shall protect human health and guarantee a basic level of medical assistance for everyone. The rights established in Article 111 of the Satversme belong to social rights, and, when implementing them, the State enjoys a broad freedom of action that can be reasonable related with the economic situation of the State. Exercise of social rights depends on the economic situation of each law-governed state and resources available thereto. Although Article 111 of the Satversme provides for the duty of the State to carry out measures for protection of human health, this does not, however, confer a person any subjective rights to receive unlimited financial resources for ensuring his or her health. Consequently, Article 91 of the Satversme in conjunction with Article 111 of the Satversme provides for the duty of the State to ensure a just balance in allocation of financial resources to health care by taking into account the interest of certain patients to receive expensive health care services and the necessity to ensure availability of health care to the greatest possible part of the society.

The Regulation No. 899 provides for two mechanisms of reimbursement of the purchase of medical products - general and individual. The Cabinet of Ministers holds that persons, for whom purchase of medical products is reimbursed according to the general mechanism, and persons, for whom the purchase of medical products is reimbursed according to an individual mechanism, enjoy equal and comparable conditions. Although both of these mechanisms differ, none of them can be regarded as more or less advantageous for one or another person because there lay objective and reasonable consideration at the basis of each of them.

Therapeutic effect and economic feasibility of medical products to be reimbursed according to a general procedure is assessed. The individual mechanisms for reimbursement is guided towards ensuring unforeseen cases (rare diagnosis, new medical products) in case of therapeutic effect of a medical product is unknown and it is not possible to plan such payments from the State

budget in advance and to plan resources necessary for meeting the needs of a patient.

A different attitude is established because there exist two different mechanisms for reimbursement of the purchase of medical products due to certain objective reasons. If therapeutic effect and economic feasibility of a medical product has been assessed, it can be included into the list of reimbursable medical products. On the other hand, if, in extraordinary cases, a medical product has not been assessed therapeutically and economically or it has been assessed but rejected regarding inclusion of it into the list of reimbursable medical products, the State has provided for an additional mechanism. None of these two mechanisms can be regarded as more or less advantageous for a person.

The legitimate objective of the Contested Norms is not to protect the interest of the basic State budget *per se* but to ensure the rights of every person to health protection. Namely, it is assessed in each particular case whether a fair balance between the interests of those patients who need particular medicines and the interests of the society to implement the rights to health protection as guaranteed in Article 111 of the Satversme.

Under Article 111 of the Satversme, the duty of the State to ensure people with health care at the level permitted by the economical possibilities of the State and, in the case of lack of financial resources, to use mechanisms that would allow ensuring the interests of the greatest number of people possible at the best level possible. Consequently, compliance of reimbursement of the purchase of medical products with therapeutic and cost efficacy thereof is a mandatory precondition.

The procedure, according to which expenses for the purchase of medical products are reimbursed to persons, differs from the procedure of reimbursement of the purchase of medical products included into the list of reimbursable medical products based on legitimate considerations that follow from the requirements of the Regulation No. 899 regarding medicaments to be included into the list of reimbursable medical products. Medical products with non-proportionate costs are not included into the list of reimbursable medical

products, though costs for the purchase of these medicaments are reimbursed at the amount of 100 percent but not more than 10 000 lats per the time period of 12 months. By reimbursing the purchase of medical products with non-proportionate costs, the resources of the State budget meant for this would be spent for meeting the needs of a considerably narrower circle of patients.

4. The Human Rights Bureau of the Republic of Latvia (hereinafter – the Human Rights Bureau) holds that the Contested Norms do not comply with Article 91 of the Satversme.

The Human Rights Bureau indicates that the patients who have been diagnosed with a disease listed in Appendix 1 of the Regulation No. 899 and the medical product necessary for the treatment thereof is not included into the list of reimbursable medical products, as well as the patients having the same disease listed in Appendix 1 of the Regulations No. 899 and who benefit from 100 percent reimbursement of the purchase of medical products, form two separate groups of patients. Both these groups are bound by common circumstances, namely, one and the same disease, treatment of which requires respective medical products that ensure vital functions of the patient. Consequently, these persons enjoy equal and comparable conditions.

The Contested norms that provide for a limit for reimbursement of the purchase of medical products to 10 000 lats per years provide for a different attitude towards one of the above mentioned groups.

The Human Rights Bureau holds that, when assessing compliance of the Contested Norms with the principle of equality, it is necessary to take into consideration the field of law, to which these norms pertain. Reimbursement of the purchase of medical products shall be related with the rights to health care and health protection, these rights pertaining to social law. Ensuring of social rights is regarded as a duty of the State, according to international documents. The Human Rights Bureau draws attention to Article 12 of the International Covenant on Economic, Social and Cultural Rights, from which follows the duty of the State to ensure availability of medical services necessary for every person disregarding his or her economic condition, Article 13 of the European Social

Charter that obligates the State to ensure the exercise of the right to medical assistance for every person who is without adequate resources and who is unable to secure such resources either by his or her own efforts or from other sources. The Human Rights Bureau admits that the right to medical assistance, like other social rights, are closely related with economic situation and possibilities of the State. Taking into account the aforesaid, reasonable restrictions of rights are tolerable. This does not mean, however that such restrictions shall be permitted in any form. Such restrictions can only be provided by law or based on law and only insofar as they are necessary to reach a legitimate objective.

Provided that the purchase of *Sprycel* medical product is reimbursed, the difference between the price of the medical product and the reimbursement to be covered by a person using his or her own resources constitutes 2707.09 lats per month, i.e. 78 percent of the price of the medical product. Consequently, persons with average incomes are denied the possibility to obtain such medical product, the price of which constitutes a few thousand lats per package. Possibilities of I. Salova to buy the necessary medicaments are negligible or even impossible. Consequently, the Human Rights Bureau holds that the restriction provided for in the Contested Norms, which, in the case under review, limits reimbursement for the purchase, by the particular person, of medical products to 10 000 lats per year, does not ensure at least the same amount of reimbursement if compared with persons with an identical or similar diagnosis and regards it as non-proportionate for reaching the objective of reimbursement of the purchase or medical products.

5. The Ministry of Health of the Republic of Latvia indicates in the information provided by it to the Constitutional Court that the legal norms included in the Regulation No. 899 that follow from the Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medical products for human use and their inclusion in the scope of national health insurance systems.

Under the requirements of Item 1 of Section 2 of the above mentioned Directive, an application regarding inclusion of respective medical product into

the positive list of medical products covered by the health insurance systems shall be made before the competent authorities of the State by the holder of a marketing authorization. In the normative enactments of the Republic of Latvia, the holders of a marketing authorization is denominated as the holder of register certificate (owner) in accordance with the requirements of Section 1 the Directive 2001/83/EEK of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medical products for human use, the Section being related with marketing authorization. According to these requirements, Section 11 of the Regulation No. 899 provides that in order to include medicinal products and medical devices on the List of Reimbursable medicinal products, a holder (owner) of marketing authorization or an authorized representative thereof, or a wholesaler of medicinal products or medical devices, or an authorized representative thereof (hereinafter — applicant) shall submit a written application to the Medicine Pricing and Reimbursement State Agency.

According to Section 61 of the Regulation No. 899, medical products shall be included into the list of reimbursable medical products for the period of two years. Provided hat medical product market is under constant change (production of some medical products can be ceased due to different reasons, the producer of medical products decides not to offer their product in the Latvian market), it is essential to guarantee availability of the medical products to the patients. Section 12.5 of the Regulation No. 899 provides that a certification that the continuous presence on the market of the reimbursable medicinal products will be ensured until the end of the term of validity for the inclusion thereof on the List of Reimbursable medicinal products.

The second essential factor of why an application regarding inclusion of a medical product into the list of reimbursable medical products must be submitted by a producer or a wholesaler is the price of medical products. Section 57.2 of the Regulation No. 899 provides that a decision on the inclusion of a medicinal product or a medical device on the List of reimbursable medicinal products shall include basic price of reimbursement and the pharmacy (public) price for the medicinal product or medical device. In order to ensure broadest choice possible of reimbursable medical products by simultaneously creating the possibility to reimburse,

from the State budget, the costs for the purchase of medical products for the broadest circle of patients possible, the Medicine Pricing and Reimbursement State Agency assesses the price of each medical product to be included into the list of reimbursable medical products by taking into consideration the criteria provided for in the Regulation No. 899 and tries to agree with the producer or wholesaler of the medical product on price reduction (in the result of price reduction, about 1,2 million lats were saved in 2007).

When drafting the list of reimbursable medical products, it is important to ensure constant availability of the medical products and compliance of the price of the medical products with therapeutic efficiency and possibilities of the State budget.

A certain funding from the State budget is allotted for reimbursement of the purchase of medical products. It is calculated taking into consideration prognosis on the number of those patients that would be diagnosed with the diseases listed in Appendix 1 of the Regulation No. 899 and who would need medical products included into the list of reimbursable medical products, as well as calculations on average expenses for treatment of one patient. On the other hand, it is impossible to foresee the number of patients that need individual reimbursement, as well as the expenses for the treatment of these persons. Therefore no special funds are planned for individual reimbursement. Instead, a part of the resources meant for general reimbursement are used for these means. Thus the limit of individual remuneration, i.e. 10 000 lats per 12 months, has been established taking into consideration possibilities of the State budget and by balancing this limitation with average expenses for purchase of medical products.

The Ministry of Health holds that taking into consideration the conditions when the State funding provided for reimbursement of the purchase of medical products is too low to ensure reimbursement for medical products for all patients who have been diagnosed with a disease and prescribed with medicaments necessary for treatment thereof included into the medical product remuneration system, it is not reasonable to apply an unlimited reimbursement for individual and unplanned cases.

The Constitutional Court holds

6. Article 91 of the Satversme provides: "All human beings in Latvia shall be equal before the law and the courts. Human rights shall be realised without discrimination of any kind."

Although the application contains a request to assess compliance of the Contested Norms with Article 91 of the Satversme, if still follows from the application that compliance of the Contested Norms only with the first sentence of Article 91 of the Satversme should be assessed provided that the first sentence thereof guarantees equality of persons before the law and courts. The objective of the principle of prohibition of discrimination incorporated in the second sentence of Article 91 of the Satversme is to prevent the possibility that in a democratic and law-governed state, based on some inadmissible criterion like race, nationality or gender, the basic rights would be restricted (*see: Judgment of 14 September 2005 by the Constitutional Court in the case No. 2005-02-0106, Para 9.3*). It has not been indicated in the application, however, that the different attitude provided in the Contested Norms would be based on some inadmissible criterion. Therefore, in the framework of this case, the Contested Norms shall be analyzed in the context of the principle of equality, rather than that of prohibition of discrimination. Moreover, the Contested Norms shall be analyzed at the extent of the claim included in the application and only in relation to the procedure for reimbursement of the purchase of medical products meant for outpatient treatment, without assessing the procedure for reimbursement of the costs towards purchase of medical devices.

7. The principle of equality provided in the first sentence of Article 91 of the Satversme should guarantee existence of a common legal procedure. Namely, its task is to ensure implementation of such requirement of a law-governed state as overall influence of laws on all persons and application of law without any privileges. It guarantees complete effect of the law, objectivity and impassiveness of its application as well as the fact that nobody is allowed not to observe the instructions of the law (*see: Judgment of 14 September 2005 by the*

Constitutional Court in the case No. 2005-02-0106, Para 9.1). Such unity of legal procedure, however, does not mean levelling because "equality permits a differentiated approach if it can be justified in a democratic society" (*see: Judgment of 26 June 2001 by the Constitutional Court in the case No. 2001-02-0106, Para 6 of the Concluding Part*).

When interpreting Article 91 of the Satversme the Constitutional Court has recognized that the principle of equality forbids to the State institutions passing such norms, which without a reasonable ground permit a differentiated attitude to persons, who are in equal and under certain criteria comparable circumstances. The principle of equality permits and even requires a differentiated attitude towards persons, who are in different circumstances as well as permits a differentiated attitude towards persons, who are in equal circumstances, if there is an objective and reasonable basis for it (*see, e.g.: Judgment of 3 April 2001 by the Constitutional Court in the case No. 2000-07-0409, Para 1 of the Concluding Part and Judgment of 11 November 2005 by the Constitutional Court in the case No. 2005-08-01, Para 5*). A different attitude has no objective and well-grounded reason if it does not have a legitimate objective or if the chosen means and advanced objectives are not proportionate (*see: Judgment of 23 December 2002 by the Constitutional Court in the case No. 2002-15-01, Para 3 of the Concluding Part*).

Consequently, in order to assess whether the Contested Norms comply with the principle of equality included in the first sentence of Article 91 of the Satversme, it is necessary to establish:

1) whether and what persons (groups of person) enjoy equal and, according to certain criteria, comparable conditions;
2) whether the Contested Norms provide for an equal or different attitude towards these persons;
3) whether such attitude has an objective and well-grounded reason, namely, whether it has a legitimate objective and whether the principle of proportionality has been observed.

8. The Contested Norms are related with persons mentioned in Section 92 of the Regulation No. 899. In order to establish whether these persons enjoy equal and, according to certain criteria, comparable conditions if compared with the persons mentioned in Chapter II of the Regulation No. 899, it is necessary to establish what mechanisms of reimbursement of the purchase of medical products are provided for in the Regulation No. 899.

The Regulation No. 899 provides for two mechanisms of reimbursement of the purchase of medical products: general and individual one.

8.1. In the frameworks of the general mechanism, the purchase medical product that are included into the list of reimbursable medical products and meant for treatment of diagnosis included in Appendix 1 of the Regulation No. 899 is reimbursed. The list of reimbursable medical products is compiled by the Medicine Pricing and Reimbursement State Agency (Section 11 of the Pharmaceutical Law and Section 10 of the Regulation No. 899) in accordance with the fundamental principles mentioned in Section 6 of the Regulation No. 899, and the list consists of three parts: List A, List B and List C. List A, according to the criteria provided in Section 23 and Chapter V of the Regulation No. 899, provides for mutually replaceable medical products within the framework of the titled of medical products or a group thereof, as well as mutually replaceable medical devices. List B, according to the criteria provided in Section 23 and Chapter V of the Regulation No. 899, includes such medical products and medical devices having no replaceable medical product or medical device as its counterpart. List C, according to the criteria provided in Section 23 and Chapter V of the Regulation No. 899, includes such medical products and medical devices, the costs of which per one patient constitute 3000 lats per year and provisions of prescription of which, according to Section 55 of the Regulation No. 899, are insufficient in order to limit the number of patients taking into consideration the resources allocated for the reimbursement.

The costs towards the purchase of reimbursable medical products are covered to a certain extent taking into consideration the nature and level of gravity of the disease. As provided for in Section 4.1 of the Regulation No. 899, medical produces shall be reimbursed at the amount of 100 percent, 90 percent, 75 percent and 50 percent.

8.2. The individual mechanism provides for reimbursement of the costs towards the purchase of medical products that are not included into the list of reimbursable medical products for individual persons.

Under Section 92 of the Regulation No. 899 the State Mandatory Health Insurance Agency, based on the application of a patient supplemented by the decision made by the Council of Physicians of the relevant field, is entitled to take a decision regarding the reimbursement for purchase of medicinal products or medical devices for individual patients. The above-mentioned expenses shall be reimbursed within the range of funding allocated for the reimbursement of expenses towards purchase of medicinal products in the following cases. First of all, the diagnosis is not included in Annex 1 to these Regulations, and the treatment of the definite disease without administration of the specific medicinal product does not maintain patient's life functions. Secondly, the diagnosis is included in Annex 1 to these Regulations, and none of the medicinal products included on the list of reimbursable medicinal products and medical devices are appropriate for the maintenance of life functions (the administration of medicinal products and medical devices not included on the List of reimbursable medicinal products for the definite diagnosis is required). In this case, the State Mandatory Social Insurance Agency adopts a decision regarding reimbursement of the costs towards the purchase of medical products at the amount of 100 percent. The Contested Norms provide, however, that the purchase of medical products is reimbursed for individual persons at the amount not exceeding 10 000 lats per one patient for the time period of 12 months. If the expenses exceed 10 000 lats, the difference shall be covered by the patient on the receipt of the medical product in the pharmacy.

8.3. The Constitutional Court holds that the opinion of the Applicant that the persons mentioned in Section 92.2 of the Regulation No. 899 and the persons mentioned in Chapter II of the same Regulation enjoy equal and comparable conditions is grounded because both groups of persons have been diagnosed with one and the same disease (chronic, life-threatening disease or a disease that results in a severe, irreversible disability) and both groups of persons need, for treatment of their disease, to use medical products to maintain their vital functions. The Human Rights Bureau also agrees with this viewpoint. Moreover,

the Constitutional Court holds that the persons mentioned in Section 92.1 of the Regulation No. 899 (whose diagnose has not been included into Appendix 1 of the Regulation No. 899) enjoy equal and comparable conditions if compared to the persons mentioned in Section II of the same Regulation because both these groups of persons have been diagnosed with a chronic, life-threatening disease or a disease that results in a severe, irreversible disability, and the treatment of the disease requires the use of the respective medical products to maintain the patient's vital functions.

Consequently, the persons mentioned in Section 92 of the Regulation No. 899 and the persons mentioned in Chapter II of the Regulation No. 899 enjoy equal and comparable conditions.

9. The persons mentioned in Section 92 of the Regulation No. 899, as well as the persons mentioned in Chapter II thereof have the right to receive reimbursement of the purchase of medical products at a certain amount in accordance with the diagnosis. As to the individual mechanism of reimbursement, the Contested Norms, however, provide for restrictions by providing that in certain cases the costs towards the purchase of medical products per one patient shall be reimbursed at the amount that does not exceed 10 000 lats for the period of 12 months. No such restriction exists in the general mechanism or reimbursement, as well as such medical products are included into the list of reimbursable medical products that exceed 10 000 lats per one patient for the period of 12 months.

Consequently, the Contested Norms provide for a different attitude towards the persons who enjoy equal and comparable conditions.

10. In order to establish whether the different attitude has an objective and well-grounded reason, it is necessary to assess whether it has a legitimate objective and whether the principle of proportionality has been observed.

Taking the above into consideration the Constitutional Court recognizes that it is not always possible to assess conformity of a concrete restriction of a fundamental right with the Satversme only in the aspect of the first sentence of Section 91 of the Satversme. First of all it shall be taken into consideration that the equality principle, determined in the first sentence of Satversme Section 91 very often shall be applied together with other fundamental rights. Especially because one cannot often deduce how to adjudicate a case just on the basis of this principle (*see: Judgment of 8 November 2006 by the Constitutional Court in the case No. 2006-04-01, Para 15*). It has also been recognized in legal literature that often it is not possible to arbitrate if based only on this principle (*see: Langenbuhere K. Tiesnešu tiesību attīstība un iztulkošana. Rīga: Tiesu namu aģentūra, 2005, pp. 158*).

When establishing whether the legal norms comply with the principle of equality, one shall take into consideration the field of law, in which it is included. The nature of the Contested Norms, *inter alia*, also its connection with other norms of the Satversme and their place in the system of fundamental rights, inevitably influence the scope of the control, realized by the Constitutional Court (*see: Judgment of 8 November 2006 by the Constitutional Court in the case No. 2006-04-01, Para 15.2*).

11. The Cabinet of Ministers indicates that the different attitude has a legitimate objective, i.e. to protect the rights of other persons, namely, the rights to health protection. The Human Rights Bureau also holds that the objective of the different treatment is to ensure the rights of other person to health protection.

11.1. The right to health protection at the constitutional level have been enshrined in Article 111 of the Satversme that provides that the State shall protect human health and guarantee a basic level of medical assistance for everyone. The Constitutional Court has already indicated that the obligation of the state is not only to undertake measures of protecting health of the people but also to abstain from activities, limiting the possibilities of persons taking care of their health themselves. Thus, in compliance with Article 111 of the Satversme, every person to a

certain extent has the right of undertaking measures he/she considers necessary to protect his/her health (*see: Judgment of 22 October 2002 by the Constitutional Court in the case No. 2002-04-03, Para 1 of the Concluding Part and Judgment of 23 April 2004 by the Constitutional Court in the case No. 2003-15-0106, Para 6*).

11.2. Likewise, the Constitutional Court has indicated that the content of Article 111 of the Satversme shall be interpreted as being read in conjunction with Article 89, which establishes: "The State shall recognize and protect fundamental human rights in accordance with this Constitution, laws and international agreements binding upon Latvia (*see: Judgment of 22 October 2002 by the Constitutional Court in the case No. 2002-04-03, Para 1 of the Concluding Part, Judgment of 27 June 2003 by the Constitutional Court in the case No. 2003-04-01, Para 1 of the Concluding Part and Judgment of 17 January 2005 by the Constitutional Court in the case No. 2004-10-01, Para 7.1*). When interpreting the Satversme and international liabilities of Latvia, it is necessary to look for such solution that would ensure harmony thereof (*see: Judgment of 13 May 2005 by the Constitutional Court in the case No. 2004-18-0106, Para 5 of the Concluding Part*). Consequently, the international law and the practice of application thereof may serve as the means for establishing the content of legal norms and principles established in the Satversme.

Article 25 of the UN Universal Declaration of Human Rights provides that everyone has the rights to a standard of living adequate for the health and well-being of himself and of his family, including medical care.

Article 12 of the UNO International Covenant on Economic, Social and Cultural Rights provides that the State Parties of the present Covenant recognize the rights of everyone to the enjoyment of the highest attainable standard of physical and mental health. The set of measures that the Party States must undertake for full implementation of the rights must contain such measures that are necessary to ensure prevention, treatment and control of diseases, inducing epidemic, endemic, occupational and other diseases, as well as creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The UNO Committee for Economic, Social and Cultural rights that has been established with a view to supervise implementation of the UNO International Covenant on Economic, Social and Cultural Rights in the Member States has interpreted the rights to health protection in its General Comment No. 14 "The right to the highest attainable standard of health" (*see: The right to the highest attainable standard of health: 11/08/2000. E/C.12/2004/4. CESCR. Substantive issues arising in the Rights. General Comment Nr. 14*). In this comment (hereinafter – the General Comment No. 14) it has been indicated that the rights to health protection shall not be interpreted as the right be well. The rights to health protection include both, certain freedoms and rights. Freedoms mean, for instance, the fact that everyone can freely control his or her own health and body, as well as be free from interruption of other persons into certain processes, for example, a person cannot be treated without his consent. On the other hand, the rights include the rights to availability of such medical assistance system that would ensure equal possibilities to reach the highest health level possible for everyone. It must be taken into consideration, however, that the State can not undertake full responsibility for the possibilities of a person to reach the highest health level possible if it is determined by genetic factors, resistance or non-resistance of a particular person against different diseases, as well as unhealthy life style. Consequently, the rights to health protection comply with the duty of the State to ensure availability and accessibility of medical care institutions, services, equipment and medical products, as well as other conditions that affect the possibility to reach the highest health level possible.

Consequently, the duty of the State to carry out measures that are necessary to protect human health, including ensuring of availability and accessibility of health care services and medical products follows from the rights to health protection.

11.3. The Cabinet of Ministers, in its reply, explains that the objective of the Contested Norms is to ensure balance between the interests of all patients to receive primary health care of a certain level and the interests of patients in individual and extraordinary cases. If, in the frameworks of an individual

reimbursement mechanism, no restrictions would be established, there would form an unfair, unequal and non-proportionate attitude of the State towards other patients. Namely, it would not be possible to satisfy applications of patient submitted to State reimbursed institutions in order to receive reimbursement of the purchase of medical products in accordance with the list of reimbursable medical products because the budget resources of medical assistance would already be spent when reimbursing the costs towards the purchase of medical products for individual persons. The Cabinet of Ministers has indicated that, if no such restrictions would be established, the number of those patients who could receive individual reimbursement would be reduced because the resources allocated would be at an insufficient amount. Consequently, the restriction established in the Contested Norms is guided towards ensuring a possibility for the broadest circle of patients possible to receive effectively reimbursement of the purchase of medical products by thus favouring health protection in accordance with Article 111 of the Satversme.

Since the State has the duty to ensure accessibility of medical products, and the restriction included into the Contested Norms is also guided towards the objective to ensure accessibility of medical products to the largest number of persons possible, the different attitude has a legitimate objective, i.e. to ensure the rights to health protection of other persons.

12. As it follows from the application, the Applicant holds that by providing, in the Contested Norms, a different attitude, the principle of proportionality is not observed. The Contested Norms provide for a different treatment depending on the fact whether the medical product necessary for treatment of a certain disease is or is not included into the list of remunerable medical products. Medical products are included into this list only in the case if their therapeutic and economic efficiency has been examined. This, however, is a formal criterion because it does not depend on the will and activities of a particular patient. Moreover the fact that the medical product has not been included into the list of remunerable medical products does not mean that they

are inefficient. Efficiency of medical products can be judged only after assessment thereof. The Applicant holds that the amount of remuneration of the costs towards the purchase of medical products can only be restricted if it would apply also to the general mechanism of reimbursement of the purchase of medical products.

The Human Rights Bureau, too, holds that the principle of proportionality has not been observed. The fact that efficiency of medical products to be reimbursed according to general procedure is not sufficient or proved enough may not serve as the basis for restriction of the amount of reimbursement. In the frameworks of an individual reimbursement mechanism, each case is assessed separately since each of such cases is extraordinary. Moreover, in the case if a person needs expensive medical products and he or she has to cover the difference between the price and the reimbursement amount, the opportunity to purchase this medical product is small or none. Since the Contested Norms do not ensure that all persons receive the same amount of reimbursement for the purchase or medical products for treatment or an identical or similar diagnosis, the principle of proportionality has not been observed.

12.1. According to the Constitutional Court, in order to establish whether the principle of proportionality has been observed when establishing a non-proportionate attitude, it is necessary to take into consideration connection of the Contested Norms not only with the norms mentioned in the application but also with that of the Satversme.

12.1.1. The Contested Norms are related with the rights to health protection established in Article 111 of the Satversme. Moreover, the Contested Norms have an impact to the rights of a person to health protection conferred thereto, as well as the rights of other persons to health protection. Therefore it is necessary to assess the duties of the State that follow from the rights of persons to health protection.

The Contested Norms regulates the duty of the State to ensure access of persons to medical products. This duty follows from the rights to health care. However, the practice of application of the norms of international human rights

shows that the duty to ensure all necessary medical products for free does not follow from the rights to health protection. Neither such duty follows from the rights of everyone to live and the rights to private life (*see: Decisions on admissibility of the European Court of Human Rights in the cases: Nitecki v. Poland, decision of 21 March 2002 on the admissibility of the application; Sentges v. the Netherlands, decision of 8 July 2002 on the admissibility of the application; Pentiacova and Others v. Moldova, decision of 4 January 2005 on the admissibility of the application*).

It has also been indicated in the General Comment No. 14 that the duty of the State is to provide persons with an access to medical products, especially to the most important medical products enumerated by the World Health Organization. This duty also includes the duty of the State to ensure financial availability of medical products. However, in the General Commentary, it has not been indicated that everyone has the rights to request full reimbursement of the necessary medical products.

12.1.2. The duty of the State to observe, protect and ensure the rights of persons follow from civil and political rights, as well as economic, social and cultural rights. The duty to observe the basic rights implies the duty of the State not to interfere with the rights of persons. The duty to protect the basic rights means the duty of the State to protect the basic rights of a person from interference of other private persons with them. On the other hand, the duty to ensure the basic rights implies the duty of the State to take certain measures for the exercise of the basic rights *(The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, para 6. See also: Judgment of 3 April 2008 by the Constitutional Court in the case No. 2007-23-01, Para 7*).

The duty to ensure access to medical product shall be qualified as the duty to ensure the basic rights and it can as such depend on the resources at the disposal of the State. It has been recognized in the International Covenant on Economic, Social and Cultural Rights. The first part of Article 2 of this Covenant provides that each State Party to the present Covenant undertakes to take steps to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by

all appropriate means. The Constitutional Court has also recognized that the State may not refuse from implementing its economic, social and cultural rights established in the Satversme, however, the extent of implementation of these rights depend of the resources at the disposal of the State (*see: Judgment of 13 March 2001 by the Constitutional Court in the Case No. 2000-08-0109, the Concluding Part and Judgment of 11 December 2006 by the Constitutional Court in the case No. 2006-10-01, Para 14.2 and 14.3*).

12.1.3. In the result of the fast development of modern medicine and science, an extensive list of medical products and devices has emerged for treatment of different diseases. However, the financial resources of the State are limited and the State cannot reimburse the costs of each inhabitant towards the purchase of the necessary medical products, medical devices and health treatment. Allocation of resources for one group of patients means that these resources are denied to other groups. Therefore, almost each state must deal with the difficult question regarding allocation of resources. Consequently, states may decide who shall receive the reimbursement, under what circumstances and for what kind of treatment.

No universal criteria exist in the world that would allow determining priorities. Therefore the State enjoys a broad freedom of action in this respect. The European Court of Human Rights has also indicated that, when deciding issues regarding allocation of a limited amount of resources, the State enjoys a broad freedom of action (*see: Decisions regarding admissibility by the European Court of Human Rights in the cases: Nitecki v. Poland, decision of 21 March 2002 on the admissibility of the application; Sentges v. the Netherlands, decision of 8 July 2002 on the admissibility of the application; Pentiacova and Others v. Moldova, decision of 4 January 2005 on the admissibility of the application*). Such activities, however, are not unlimited.

First of all, regardless of the level of the economical development, the state has the obligation of undertaking activities to reach the ensurance of the social rights at least on the minimum level by making use of all the means at its disposal (*see: Judgment of 14 January 2004 by the Constitutioanl Court in the case No. 2003-19-0103, Para 8*).

Secondly, it has been emphasized in the General Comment No. 14 that an inadequate allocation of resources for health care is inadmissible. The State must first of all develop primary health care and prevention system, which would be advantageous for the majority of the society, rather than to provide expensive health care services that are often available to a very small part of the society.

It has also been admitted in jurisprudence that resources should be used with a view to provide the greatest benefit possible for the largest number of persons possible If resources are limited, it is necessary to elaborate such mechanism that would ensure optimal use of resources available (*see: Alvarez-Castillo F., Ravindran T. K. S., de Pinho H. Priority Setting. In: The Right Reforms? Health Sector Reforms and Sexual and Reproductive Health. Ravindran T. K. S., de Pinho H (eds). South Africa: Women's Health Project, School of Public Health, University of the Witwatersrand, 2005, p. 164*). This means that it is necessary to balance the interests of separate persons and the entire society. One cannot admit a situation in the field of social rights that any group of the society, after having requested the State to ensure certain medical services free of charge, would gain more benefit if compared to other groups of the society. If the financial resources of the State are limited, then the main focus must be made on the welfare of the society (*see: Annus T., Nompter A. The rights to health protection in the Estonian Constitution. Juridica International, Nr. VII, 2002, pp. 120–121).*

The Human Rights Bureau, it its opinion, has drawn attention to the necessity to protect the rights of the entire society (*see: case materials, Vol. 2, pp 6*).

Consequently, the State has the duty to ensure an efficient use of resources and to achieve a fair balance in allocation of financial resources provided for health care, by observing the necessity of separate patients to receive expensive health care services and the general necessity to ensure availability of health care for the greatest part of the society possible.

12.2. The Cabinet of Ministers has indicated in its reply that the system of reimbursement of medical products in Latvia has been formed taking into

consideration the fact that primary health care is the main part of health care, which is based on scientific and practical methods and that must be accessible to the inhabitants. The system of reimbursement of the purchase of medical products has been formed as one of the mechanisms for ensuring one of the principles of primary health care, which is accessibility and justice. This concerns patients with severe and chronic diseases. Full medical treatment of outpatients allows preventing worsening of the health conditions of a patient and his or her treatment in a hospital. Therefore, in Latvia, there has been a medical products reimbursement system introduced for patients with severe or chronic diseases.

Pharmaceutical features of medical products to be reimbursed according to general procedure have been assessed, namely, their therapeutic efficiency, compliance to certain schemes and guidelines for treatment of particular diseases, as well as other important factors (see: Para 22, 23 and 24 of the Regulation No. 899 and Chapter VI). These medical products have also been evaluated economically, namely, their costs and effect on the State resources allocated for such kind of reimbursement, their therapeutically and cost efficiency in comparison with another available therapeutic method have been assessed, as well as the prices thereof in Latvia and in other European Member States have been analysed (see: Para 22, 23 and 24 of the Regulation No. 899 and Appendix 3).

When assessing medical products meant for ensuring vital functions before inclusion of them into the list of reimbursable medical products, survival index is taken into consideration, namely, it is being assess at what extent a particular medical product prolongs live in comparison with other therapeutic method available for treatment of the respective disease (usually – widely available therapeutic method). This means that, according to the list of reimbursable medical products, the costs of a patient for only such medical products that the competent State institution has recognized as therapeutically and economically feasible are reimbursed for a particular diagnosis (a patient), rather than any medical product chosen by the patient and any medical product

for any price is reimbursed, provided that the costs for the purchase of medical products are reimbursed at the amount of 100 percent.

When including medical products into the list of reimbursable medical products, it is being calculated at what extent the new costs exceed the planned ones. Taking into consideration the difference between survival indices and costs, additional expenses per one life-year acquired in the result of treatment is being calculated (this is cost efficiency increase coefficient). In other states, too, similar methods are applied when forming a list of state-reimbursed medical products *(see: Alvarez-Castillo F., Ravindran T. K. S., de Pinho H. Priority Setting. In: The Right Reforms? Health Sector Reforms and Sexual and Reproductive Health. Ravindran T. K. S., de Pinho H (eds). South Africa: Women's Health Project, School of Public Health, University of the Witwatersrand, 2005, p. 140*). According to Item 46.2 of the Regulation No. 899, on the List C, medicinal products and medical devices shall be included if cost-effectiveness increase ratio for a life-year acquired in addition does not exceed the cost-effectiveness increase ratio for medicinal products and medical devices already included on the List.

On the other hand, in the case of reimbursement of the costs for the purchase of medical products for individual persons, therapeutic efficiency of the medical product, its compliance to the schemes and guidelines for treatment of the respective diseases and other important factors have not been assessed. Moreover, no positive cost evaluation of the medical product is provided. The individual mechanism for reimbursement is guided towards ensuring treatment in extraordinary cases (rare diagnosis, new medical products), if therapeutic efficiency of products (including survival indices, which in separate cases may equal with zero) is not yet known and it is not possible to foresee and plan budget resources for meeting the needs of patients.

In the case under review, too, based on Article 4 of the Medical Law and Section 62.2 of the Regulation No. 899, the Medicine Pricing and Reimbursement State Agency has rejected the application of the distributor of medical products to include the medical product *Sprycel* (*Dasatinibum, ATC L01XE06)* into the list of reimbursable medical products because no results of chemical research have

been submitted. Neither the Medicine Pricing and Reimbursement State Agency has received any information regarding therapeutic efficiency of the medical product in the case of Z94.8 diagnosis (*see: case materials, Vol. 1, pp. 149 - 159 and Vol. 2, pp. 12 - 22*).

Consequently, it can be concluded that the system of reimbursement of medical products is based on assessment of therapeutic and cost efficiency. Only such medical products are included into the list of reimbursable medical products, the therapeutic and cost efficiency of which have been proved. On the other hand, in the case of individual mechanism of reimbursement of the costs for the purchase of medical products, assessment of therapeutic and cost efficiency of medical products is insufficient or is not sufficiently proved. When providing for a different attitude, the State is trying to achieve effective use of the resources at its disposition in the system of reimbursement of medical products and to ensure the rights of the largest part of the society possible to health protection.

Taking into consideration the aforesaid, the Contested Norms are an appropriate measure for reaching the legitimate objective.

12.3. Since 2005, the system of reimbursement of the costs for the purchase of medical products in Latvia is being developed according to the conception "On Financial Resources to Ensure Accessibility of Medical Products for Treatment of Outpatients in Latvia for the Following Five to Ten Years, the Role and Responsibility of the State in this Process" (hereinafter – the Conception). The Conception was approved by the Order of 20 December 2004 by the Cabinet of Ministers No. 1002 "Regarding the Conception on Financial Resources to Ensure Accessibility of Medical Products for Treatment of Outpatients in Latvia for the Following Five to Ten Years, the Role and Responsibility of the State in this Process" (*see: http://polisis.mk.gov.lv*).

Under the Conception, drawing up of a list of remunerable medical product was launched on 2005 and fully terminated on 2007. The list was created for the diagnoses that were not funded for the period of two years due to the lack of resources. From 1 January 2007, the amount of reimbursement in the case of several diseases was increased. List of reimbursable medical products

appropriate for medical systems have been drawn up for several groups of diseases by emphasizing those groups, the sickness and mortality rate of which are higher. Likewise, those medical products that have been purchased according to a centralised order have also been included into the list of reimbursable medical products. From 1 January 2005, reimbursement of medical products for individual patients was launched by thus providing the patients with severe and chronic diseases with a possibility to receive State assistance when purchasing medical products in extraordinary cases, for instance, if a patient has been diagnosed with a rare disease that is not included into the reimbursement system or the medical products necessary for its treatment has not been included into the list of reimbursable medical products. 2 percent from the annual State budget are allocated for such cases of reimbursement of medical products (*see: case materials, Vol. 1, pp. 136 – 141*).

The funding of the State budget allocated for remuneration of medical products is gradually increased. As it follows from the information provided by the Cabinet of ministers, there were 19.8 million lats allocated for remuneration of the purchase of medical products in 2004, 30.4 million lats in 2005, 42.7 million lats in 2006, 61.3 million lats in 2007 and 66.3 million lats in 2008 (*see: case materials, Vol. 1, pp 139 and Appendix 4 of the Law "On State Budget for 2008"*). Irrespective the increase of the funding, the Ministry of Health indicates that deficit of 7 million lats is planned for the system of reimbursement of medical products, which causes problems regarding reimbursement of the medical products included into the list of reimbursable medical products (*see: case materials, Vol. 2, pp 10*).

As it was already indicated, the State enjoys a broad freedom of action when deciding on allocation of resources. It was also concluded that therapeutic and cost efficiency of medical products may also serve as the reason for a different attitude. It was recognized by, for instance, the Federal Constitutional Court of Germany by indicating that the fact that the State refuses to reimburse medical products, the therapeutic and cost efficiency of which has not been assessed, even if this medical product is necessary for ensuring vital functions of

a patient (*see: Judgment of 5 March 1997 by the Federal Constitutional Court of Germany in the case No. Nr. 1 BvR 1068/96*).

Consequently, it can be concluded that the State has the right not to reimburse the costs towards the purchase of such medical products, the therapeutic and cost efficiency of which has not been assessed or proved. The State, however, has chosen to provide assistance for the persons who do not need such help, although the assistance is limited.

Taking into consideration the aforesaid, the Constitutional Court concludes that the State has selected the most lenient measure possible.

12.4. When assessing the rights of the legislator and the Cabinet of Ministers to provide for the amount of social assistance, it is necessary to take into consideration the fact that the minimum amount of reimbursement of medical products is determined by the State budget that is often politically assessed.

The Constitutional Court has already indicated that it is not possible to assess financial possibilities of the state, economic situation, priorities of law policy and particular needs of certain social groups by means of legal argumentation. These considerations affect the decision of the legislator and the Cabinet of Ministers when providing for services and establishing the amount thereof (*see: Judgment of 11 December 2006 by the Constitutional Court in the case No. 2006-10-01, Para 14.2 and 14.3*).

The courts of other states have also recognized that court proceedings is not appropriate measure for dealing with an issue regarding priorities in the health care system (*see: King J. A. The Justiciability of Resource Allocation. The Modern Law Review, 2007, Vol. 70, Number 2, p. 199*).

Consequently, the possibilities of the Constitutional Court to assess whether, in the case under review, the benefit gained by the society is greater than the harm done to a person re restricted. The Constitutional Court, however, can assess whether, in this case, the established restriction is well-grounded.

12.4.1. Certain funding from the State budget is allocated for reimbursement of medical products. The amount of the resources allocated is

calculated taking into consideration prognosis regarding the number of those patients that have been diagnosed with diseases listed in Appendix 1 of the Regulation no. 899 and who need medical products included into the list of reimbursable medical products for treatment thereof, as well as calculations for average costs for treatment of one patient are taken into account. On the other hand, the number of those patients that need individual reimbursement, as well as the costs of treatment of these patients cannot be prognosticated. Therefore no extra resources are allocated for individual remuneration, whilst a part of resources allocated for reimbursement of medical products is used.

When establishing, by means of the contested norms, the limit of reimbursement at the amount of 10 000 lats per the period of 12 months for one patient, the State has tried to achieve that it would be possible to provide assistance for the largest number of patients possible. Namely, it was done by assessing possibilities of the State budget and proportionality of the restriction with average costs for the purchase of medical products. Consequently, there can be a situation formed that due to a certain restriction there is a person that cannot, in fact, by the necessary medical products. On the other hand, if there were no such restriction, there could be a situation formed that resources allocated for the mechanism of individual remuneration would be spent on assistance provision for a small number of persons who would need expensive medical products. In order to ensure a more efficient use of resources allocated for the mechanism of individual reimbursement of medical products, the particular restriction has been established. It is based on calculations of reimbursement to be allocated per one individual patient.

As it was indicated by the Ministry of Health, it is possible for the majority of patients to fully cover the costs for the purchase of medical products by means of 10 000 lats. The Ministry has substantiated its opinion by the following numbers: namely, average costs for remuneration per one individual patient constitute 6721 lats in 2005, 3767 lats in 2006, 3615 in 2007 and 2978 in eight months of 2008 (*see: case materials, Vol. 2, pp. 10*).

Consequently, it can be concluded that the restriction established by the Contested Norms is based on reasonable consideration. Therefore the Cabinet of

Ministers has managed to balance the interests of the society and that of individual persons.

12.4.2. The Applicant indicates that the different attitude has no objective reason because a person cannot influence inclusion of a medical product into the list of reimbursable medical products. The fact that the medical product has not been assessed does not mean though that it is inefficient.

Section 11 of the Regulation No. 899 provides that in order to include medicinal products and medical devices on the List of Reimbursable medicinal products, a holder (owner) of marketing authorization or an authorized representative thereof, or a wholesaler of medicinal products or medical devices, or an authorized representative thereof shall submit a written application to the Medicine Pricing and Reimbursement State Agency. The Ministry of Health explains that this provision is related with the fact that the abovementioned persons can guarantee accessibility of the respective medical products for a patient. Moreover, such mechanism allows achieving decrease of the price. Based on the procedure established in the Regulation No. 899, according to which medical products are included into the list of reimbursable medical products, as well as based on the facts obtained during the investigation process, the Medicine Pricing and Reimbursement State Agency can agree with the producer (distributor) on basic price (wholesale price) reduction for medical products to be included into the list of remunerable medical products. For instance, as it was indicated in the reply of the Ministry of Health, the initial price of the medical product *Glivec* was 1807.40 lats (120 capsules of 100 ml). The Medicine Pricing and Reimbursement State Agency managed to reduce the price to 1600 lats. In the result of this, total expenses for remuneration of the medical product *Glivec* was reduced by 150 000 lats, which means that assistance was provided for more than 1000 patients in accordance with the list of reimbursable medical products, which constitutes more than 40 percent in the case of individual reimbursement (costs per one patient when reimbursing medical products from the list of reimbursable medical products constitutes 140.98 lats, prescription expenses - about 15 lats).

Moreover, it is necessary to take into consideration the fact that information regarding researches that are carried out for the respective medical products is necessary in order to carry out therapeutic and economic efficiency

assessment for the medical product. The documents containing the necessary information can generally be provided by the owner of a registration certificate.

Consequently, such procedure has been established based on reasonable considerations that are guided towards efficient use of resources and the objective to ensure the rights to health protection of the greatest part of the society possible.

Consequently, it can be concluded that the different attitude established in the Contested Norms is well-grounded. Taking into consideration the aforesaid, as well as the fact that the State enjoys a broad freedom of action in the field of health protection, the Constitutional Court has no reason to question whether the interests of the society and that of individual persons have been balanced.

Since the different attitude has a legitimate objective and the principle of proportionality has been observed, the Contested Norms comply with Article 91 of the Satversme.

The Constitutional Court

Based on Articles 30 – 32 of the Constitutional Court Law

h o l d s :

Section 100 and Section 100.1 of the 31 October 2006 Cabinet Regulations No. 899 "Procedures for the Reimbursement of Expenses toward the Purchase of Medical Products and Medical Devices for the Out-Patient Care" comply with Article 91 of the Satversme (Constitution) of the Republic of Latvia

The Judgment is final and not subject to appeal.

The Judgment takes effect as on the date of publishing it.

The presiding Judge G. Kūtris