THE CONSTITUTIONAL COURT
OF THE REPUBLIC OF LATVIA

JUDGEMENT

ON BEHALF OF THE REPUBLIC OF LATVIA

in Case No. 2012-26-03

28 June 2013, Riga

The Constitutional Court of the Republic of Latvia, comprised of: chairperson of the court sitting Aija Branta, Justices Kaspars Balodis, Kristīne Krūma, Uldis Ķinis and Sanita Osipova,

having regard to an application by the Administrative District Court of the Republic of Latvia regarding initiation of a case,

on the basis of Article 85 of the Satversme of the Republic of Latvia and Para 3 of Section 16 and Para 9 of Section 17(1), as well as Section 19^1 and Section 28^1 of the Constitutional Court Law,

on 29 May 2013 examined in written procedure the case

"On Compliance of Para 3 of Section 67^1 (in the wording of 28 December 2010) of the Cabinet of Ministers Regulation of 31 October 2006 No. 899 "Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment" with the first sentence of Article 91 of the Satversme of the Republic of Latvia".

The Facts

1. On 31 October 2006 the Cabinet of Ministers adopted Regulation No. 899 "Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal

Products and Medicinal Devices Intended for Out-patient Medical Treatment" (hereinafter – Regulation No. 899).

The purpose of Regulation No. 899 is to ensure to patients with severe and chronic diseases the possibility to receive medicinal products, which are fully or partially reimbursed by the State. List C of this Regulation comprises such reimbursement medicinal products that are expensive and to which the provisions on prescribing established with regard to other medicinal products cannot be applied (hereinafter – List C).

On 28 December 2010 the Cabinet of Ministers adopted Regulation No.1216 "Amendments to the Cabinet Regulation of 31 October 2006 No.899 "Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment"" (hereinafter – Regulation No. 1216). Regulation No. 1216 added a new section, Section 67^1 to Regulation No. 899, which envisaged:

"$67.^1$ The Health Payment Centre shall refuse reimbursement of the medicinal products and medicinal devices if:

$67.^1$ 1. the particular case does not meet the requirements referred to in Para 67 of this Regulation;

$67.^1$2. the particular case does not meet the requirements regarding prescribing medicinal products or medicinal devices established in the decision by the Health Payment Centre on including medicinal products or medicinal devices on List C;

$67.^1$3. the number of patients indicated in the decision of the Health Economic Centre on including medicinal products or medical devices on List C has been reached."

With the Cabinet Regulation of 19 October 211 No. 821 "Amendments to the Cabinet Regulation of 31 October 2006 No. 899 "Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment", the words in Section 67^1 of Regulation No. 899 "the Health Payment Centre" were replaced by words "the National Health Service", whereas the words "the Centre of Health Economics" were deleted from Para 3 of Section 67^1.

Thus, since 11 November 2011 Para 3 of Section 67^1 of Regulation No. 899 envisages that the National Health Service refuses reimbursement of medicinal products and medicinal devices included on List C, if: "[..] the number of patients indicated in the decision on including medicinal products or medical devices on List C has been reached" (hereinafter – the contested norm).

2. The Administrative District Court (hereinafter – the Applicant Court) notes that contested norm is incompatible with the principle of equality that the first sentence of Article 91 of the Satversme of the Republic of Latvia (hereinafter – the Satversme) comprises.

The contested norm, allegedly, envisages adoption of a mandatory administrative act. Therefore it is impossible to depart from the composition of this norm in order to issue an administrative act with different content. Solely the Constitutional Court could examine the compatibility of the contested norm with a norm of higher legal force and eliminate its incompatibility with the Satversme.

It is noted in the application, by referring to the case law of the Constitutional Court, that the principle of equality allows and even demands differential treatment of persons, who are under different circumstances, as well as allows differential treatment of persons, who are under similar circumstances, in the presence of objective and reasonable grounds for that. Differential treatment has no objective and reasonable grounds, if it does not have a legitimate aim or if the relationship between the chosen measures and the aims set is not proportional. To assess, whether the contested norm complies with the principle of equality included in the first sentence of Article 91 of the Satversme, it should be established: 1) whether and which persons (groups of persons) are under similar and according to concrete criteria comparable circumstances: 2) whether the contested norm envisages similar or differential treatment of these persons: 3) whether this treatment has objective and reasonable grounds, i.e., whether it has a legitimate aim and whether the principle of proportionality has been complied with.

The applicant, who turned to the Administrative Court to protect his rights (hereinafter – the Applicant) in May 2011 was established a diagnosis, which gives the

right to receive reimbursement for medicinal products included on List C (hereinafter – the Diagnosis). Thus, the Applicant is said to be under similar and comparable circumstances with all those persons, who in 2011 also had the Diagnosis established.

The Centre of Health Economics initially had decided that in 2011 only the first 54 patients with the Diagnosis would receive reimbursement of the costs of purchasing the medicinal product *Mabthera* (*Rituximab*) (hereinafter – *Mabthera*). After these 54 patients had received reimbursement of the costs of purchasing the medicinal product *Mabthera* other patients did not receive the aforementioned reimbursement. Thus, the contested norm allowed differential treatment of the Applicant, since the right to receive reimbursement medicinal product was made dependable upon the moment when the Diagnosis was established.

It is alleged that the differential treatment envisaged in the contested norm is not proportional, since it lacks a legitimate aim. The Cabinet of Ministers has not established a mechanism that would ensure optimum use of the available resources. Likewise, the annotation to Regulation No. 1216 did not examine the impact of the contested norm upon patients' right to receive reimbursement for medicinal products.

The chosen measure – total refusal to reimburse the medicinal product – is said to be disproportional, since the costs of medicinal products included on List C are considerable. The Applicant Court holds that the Cabinet of Ministers has not considered possibilities of developing such legal mechanism that would allow the utmost possible equality in allocating the available financial resources. The chosen mechanism for granting reimbursement is said to be unfair. Some persons receive reimbursement from the State for purchase of medicinal products in full amount, whereas other persons, who are under similar and comparable circumstances with these persons, do not receive reimbursement for purchase of medicinal products at all.

3. The institution, which adopted the contested act, – the Cabinet of Ministers – does not uphold the opinion of the Applicant Court and asks the Constitutional Court to recognise the contested norm as being compatible with the first sentence of Article 91 of the Satversme.

The State, in meeting one of its basic obligations – to protect the health of inhabitants and improve quality of life, organises a complex set of measures in the field of health protection. The totality of measures of medical assistance guaranteed by the State comprises also reimbursement of the costs of purchasing medicinal products and medicinal devices from the State budget resources to patients with chronic and severe diseases.

In accordance with criteria referred to in Chapter VI of Regulation No.899, those medicinal products and medicinal devices, the costs of which for treating one patient exceed 3000 lats annually, are included on List C. The National Health Service includes medicinal products on List C after assessing their compatibility with the criteria included in Para 1- 3 of Section 46 of Regulation No. 899.

List C was introduced on the day when Regulation No. 899 came into force – on 9 November 2006. The procedure that reimbursement of medicinal products included on List C was ensured only to a limited number of patients had existed since this Regulation entered into force

The Cabinet of Ministers upholds the statement made by the Applicant Court that those patients, who have had the same diagnosis established and with regard to whom the same conditions for prescribing medicinal products are met, are under similar and comparable circumstances.

Likewise, the statement made by the Applicant Court that the contested norm in particular cases envisages differential treatment of persons, who are under similar and according to concrete criteria comparable circumstances, also is to be recognised as substantiated. I.e., the contested norm establishes differential treatment of patients, who, in accordance with it, are refused reimbursement, since at the moment of adopting the decision the number of patients included in the decision on including medicinal products or medicinal devices on List C has been exceeded.

However, the Cabinet of Ministers holds that this differential treatment can be justified. The State's obligation to ensure accessibility of medicinal products is to be qualified as the obligation to ensure fundamental rights and may depend upon resources at the State's disposal. The contested norm is said to have objective and reasonable basis, since unrestricted reimbursement for purchasing particularly

expensive medicinal products to all patients would put under threat the system of reimbursement for medicinal products established in the framework of Regulation No. 899, i.e., the resources allocated by the legislator to maintain this system would be exceeded. Hence, the legitimate aim of the restriction upon fundamental rights that follows from the contested norm is ensuring a stable and operational system of reimbursing for medicinal products. Possibilities to reimburse the costs of purchasing particularly expensive medicinal products have been envisaged in the framework of this system, and the range of medicinal products is periodically expanded.

Allegedly, the procedure established by the contested norm places considerable restrictions upon persons' rights only if, due to the fact that the previously estimated number of patients has been exceeded, a person is refused reimbursement. However, the restriction upon a person's right is said to be smaller than the total benefit to society. The contested norm had been introduced to ensure gradual reimbursement for medicinal products to all patients within the limits of the resources at the State's disposal. If services of the health care system demand considerable disbursements from the State budget, these should be introduced gradually.

The Cabinet of Ministers holds that it is impossible to reach the legitimate aim of the restriction that follows from the contested norm by other, alternative solutions, since other solutions are said to be even less favourable for patients compared to the valid legal regulation. It is alleged that the solution offered by the Applicant Court – to ensure as equal as possible allocation of financial resources – is not feasible. The costs of medicinal products included on List C are very high, and the introduction of a system like this would cause a situation, where medicinal products would be accessible only to persons with high income.

The written reply draws the attention of the Constitutional Court to the fact that the average annual increase in the number of patients is 3 to 5 per cent. Moreover, the State budget resources that are actually spent for reimbursing for the medicinal products included on Lists A, B and C of Regulation No. 899 are also increasing every year.

4. The Ministry of Health informs the Constitutional Court that List C was established with the aim to start treating patients with expensive, but effective medicinal products in the framework of limited funding. Every year, depending upon the amount of additional funding granted, the number of patients is gradually increased, thus, this treatment will be ensured to all patients needing it. Therefore the course of development of List C and the meeting of the set aim significantly depends upon the additional funding granted by the State for ensuring treatment with expensive medicinal products to an increasing number of patients.

Allegedly, the number of those patients, to whom medicinal products are reimbursed in the framework of List C, is increasing with every year. If a person initially has ben refused reimbursement of costs of purchasing medicinal products included on List, then later it is always granted.

The Ministry of Health also notes that re-allocation of financial resources in favour of other medicinal products or medicinal devices included on List C is admissible, i.e., if the resources planned for reimbursing for specific medicinal product are not used and if there are no persons requiring this reimbursement, but the resources planned for reimbursement for other medicinal products have been already spent and reimbursement for these medicinal products is requested.

5. The summoned person – **the Ombudsman of the Republic of Latvia** (hereinafter – the Ombudsman) – holds that the contested norm is incompatible with the first sentence of Article 91 of the Satversme. The arguments that the Ombudsman uses to substantiate this opinion are similar to the ones provided by the Applicant Court.

In addition the Ombudsman notes: the principle of equality means also that under similar actual and legal circumstances treatment is similar, but under different circumstances – different. However, this principle cannot be applied independently, but only together with another legal norm – in this case, Article 111 of the Satversme, Article 2 and Article 25 of the United Nations Universal Declaration of Human Rights, Para 2 of Article 2 of United Nations International Covenant on Economic, Social and Cultural Rights, Article 13 of Section II in the Preamble to the European Social

Charter, Para 1 and Para 7 of Article 168 of Treaty on the Functioning of the European Union.

The need to include into the system of reimbursement for medicinal products also expensive medicinal products is to be considered the legitimate aim of the restriction upon persons' fundamental rights. However, no sufficient grounds can be found for the disclaimer included in the contested norm that envisages differential treatment of persons when the funding for the purchase of expensive medicinal products is no longer available. Regulatory enactments do not envisage ways for finding funding necessary to reimburse the purchase of expensive medicinal products, for example, decreasing expenditure in another fields, and, allegedly, this lack of legal regulation leads to disproportional restrictions upon patients' fundamental rights.

The State is able to allocate only a limited amount of financial resources for health care. However, also under such circumstances the State should ensure fair balance between patients' need to receive expensive health care services and the general necessity to ensure accessibility of health care to as large part of society as possible. It is possible to find funding needed for the purchase of expensive medicinal products also, for example, in the framework of the European Union program "Community Action in the Field of Health (2008-2013)".

6. The summoned person – **Association of Rare Diseases "Caladrius"** (hereinafter – *Caladrius*) – notes that the contested norm is incompatible with the first sentence of Article 91 of the Satversme.

The case, allegedly, contains only the dispute, whether the differential treatment established by the contested norm may be justified by proportional need to reach the legitimate aim of the restriction. Moreover, the provisions of Article 111 of the Satversme must also be taken into consideration, i.e., that the State's obligation to ensure the existence and accessibility of health care institutions, services, equipment and medicinal products complies with a person's right to health. The State, irrespectively of its level of development, has the obligation to implement measures in order to, by employing all necessary means, achieve that economic, social and cultural rights are ensured at least on the minimum level. However, in accordance with the

contested norm, for a part of patients the medicinal products, which are necessary to ensure vital functions, are not reimbursed at all. Hence, the social rights of these patients, *inter alia*, the right to accessibility of medicinal products, are not ensured even on the minimum level.

In assessing the compatibility of the contested norm with the principle of proportionality, *Caladrius* notes: the Cabinet of Ministers has been unable to substantiate that the contested norm reached the legitimate aim of the restriction that it comprises. Firstly, unbiased and rational substantiation has not been provided – why, in case the number of patients planned for the respective year has been exceeded, it was impossible to find resources in the State budget for reimbursing the medicinal products necessary for the remaining patients. Secondly, the increase in the number of patients is a quantity that can be fairly easily forecast, so that the State would be able to estimate the amount of resources needed for reimbursing for medicinal products in the respective year.

Allegedly, the contested norm is not suitable for reaching the legitimate aim, since, for example, in 2012 approximately 2.2 million lats out of all State budget resources allocated for reimbursing medicinal products had not been used in due time. Moreover, the number of patients, who are going to be reimbursed the medicinal products included on List C, is established on the basis of the number of patients, who had started treatment in the previous year, as well as the number of those patients, whose costs for purchasing the respective medicinal products are going to be covered by the registration holder of the respective medicinal product. Thus, the number of those patients, who have had diagnoses established that require treatment with medicinal products included on List C, as well as the estimates of doctors working in the respective field are not taken into consideration.

Caladrius does not recognise that the contested norm would create such benefits to society that could outweigh the damage caused to a patient. A person’s right to health and life are to be recognised as being such values that cannot be subject to considerations regarding effective use of financial resources.

7. The summoned person – **the Association for Supporting Leukaemia Patients** – notes that the contested norm is incompatible with the first sentence of Article 91 of the Satversme.

Those diseases that are treated with medicinal products included on List C, *inter alia*, leukaemia and lymphoma, are chronic, severe and practically incurable. The progression of these diseases in all cases poses serious threat upon human life; thus, timely use of the necessary medicinal products is of decisive importance in saving lives. The Association's current experience shows that the situation, where patients cannot receive the medicinal products they need because the quotas for medicinal products have been exhausted, occurs every year, and sometimes it develops already during the first half of the year.

The Association for Supporting Leukaemia Patients also notes that in the case under examination the provisions of Article 93 and Article 111 of the Satversme should also be taken into consideration. The conclusion that lack of financial resources cannot be used as a legal argument for a violation of social rights allegedly follows from these norms.

The Association upholds the opinion expressed by the Cabinet of Ministers on which persons in the case under review are under similar and according to concrete criteria comparable circumstances, as well as the fact that the contested norm causes a differential treatment of patients, who, in accordance with the norm, have been refused reimbursement for the medicinal product.

However, the Association for Supporting Leukaemia patients does not uphold the opinion that the restriction to fundamental rights included in the contested norm is proportional. The whole of society is interested in ensuring the necessary medicinal products to all patients in due time. If the necessary treatment is not started timely, then the number of patients with untreated and severe diseases increases, and, correspondingly, later additional expenditure arises in treating these patients. A situation, where a part of patients do not receive reimbursement for medicinal drugs that are needed to keep them alive only because their disease has been diagnosed later than for some other patients, is not commensurate, and more commensurate and better

solutions could be chosen for allocating resources envisaged for reimbursing for medicinal products.

The medicinal products included on List C are very expensive, and, essentially, a situation, where the patients themselves could purchase them using own means, is not even possible. Therefore the argument advanced by the Cabinet of Ministers that an alternative to the contested norm could be partial exclusion of medicinal products from List C or introduction of patients' co-payment, is said to be inconsiderate.

The legitimate aim of the restriction upon fundamental rights that the contested norm comprises could be reached also by maintaining the need to define the number of patients, who will be reimbursed for the medicinal products included on List C. However, at the same time budget resources for emergency cases should be planned, in case the said number of patients is exceeded.

8. The summoned person – **Solvita Olsena, doctor of the science of law,** – notes that the contested norm is incompatible with the first sentence of Article 91 of the Satversme.

Similarly to the Applicant Court and the Cabinet of Ministers, S. Olsena finds that the contested norm envisages a differential treatment of persons, who are under similar and comparable circumstances. However, S.Olsena, in difference to the opinion expressed by the Cabinet of Ministers, notes that the contested norm places disproportional restrictions upon persons' fundamental rights.

Since the adoption of the contested norm, legally substantiated and independently verifiable criteria that should be met in defining or changing the number of recipients of medicinal products included on list C have not been elaborated and adopted. This fact is said to prove that in the process of organising the system of reimbursing for medicinal products, the principles of justice and equality have not been paid sufficient attention to.

The producer of medicinal product, who has submitted the application for registration, makes provisional and inaccurate estimates of the number of patients. Thus, the possibility that only part of the patients, instead of all patients needing the medicinal products will receive them is allowed from the very beginning. Allegedly,

legal acts do not envisage the obligation of the National Health Service to identify regularly the actual number of patients, for whom the medicinal products included on List C are essential for maintaining their health.

The aim of the system of reimbursement medicines is said to be ensuring persons' rights, not to protect the State budget. Thus, references to insufficiency of the State budget resources are inadmissible. The principle of fair allocation of the State resources is envisaged by the principle of a democratic state, enshrined in Article 1 of the Satversme. Whereas the obligation to allocate the maximum of necessary resources for health care is said to be envisaged by Article 111 of the Satversme.

The obligation to ensure the right to health protection obliges the State to implement all necessary measures to exercise this right. The Cabinet of Ministers and the Saeima, allegedly, have not sufficiently fulfilled their obligation to implement appropriate measures to ensure that persons can exercise their right to health. For a number of years already the Cabinet of Ministers prepares and submits to the Saeima such draft budgets that allocate fewer resources for health care than are necessary.

The Findings

9. The first sentence of Article 91 of the Satversme provides" "all human beings in Latvia shall be equal before the law and the courts."

The principle of equality enshrined in the first sentence of Article 91 of the Satversme must guarantee the existence of a uniform legal order. I.e., its task is to ensure that such requirement of a judicial state as encompassing impact of laws upon all persons and application of law without any kind of privileges. It also guarantees full effect of law, objectivity and impartiality in its application, as well as that nobody is allowed to disregard prescripts of law (*see Judgement of 14 September 2005 by the Constitutional Court in Case No. 2005-02-0106, Para 9.1).* However, such uniformity of legal order does not mean levelling, since "equality allows differential treatment, if it is justifiable in a democratic society (*Judgement of 26 June 2001 by the Constitutional Court in Case No. 2001-02-0106, Para 4 of the Findings).*

The Constitutional Court, in interpreting Article 91 of the Satversme, has recognised that the principle of equality prohibits state institutions from adopting such norms that without reasonable grounds allow differential treatment of persons, who are under similar and according to particular criteria comparable circumstances. The principle of equality allows and even demands differential treatment of persons, who are under different circumstances, as well as allows differential treatment of persons, which are under similar circumstances, if there are objective and reasonable grounds for it (*see, for example, Judgement of 3 April 2001 by the Constitutional Court in Case No. 2000-07-0409, Para 1 of the Findings, and Judgement of 11 November 2005 in Case No. 2005-08-01, Para 5)*. Differential treatment does not have objective and reasonable grounds, if it lacks a legitimate aim or if the relationship between the chosen measures and the set aims is not proportional (*see Judgement of 23 December 2002 by the Constitutional Court in Case No. 2002-15-01, Para 3 of the Findings*).

Hence, to examine, whether the contested norm complies with the principle of equality included in the first sentence of Article 91 of the Satversme, it must be established:

1) whether and which persons (groups of persons) are in similar and according to particular criteria comparable circumstances;
2) whether the contested norm envisages similar or differential treatment of these persons;
3) whether such treatment has objective and reasonable grounds, i.e., whether it has a legitimate aim, and whether the principle of proportionality has been complied with.

10. Regulation No. 899 envisages two mechanisms of reimbursing for medicinal products: general and individual. The case under review does not pertain to the mechanism of individual reimbursement.

Those medicinal products that are included on the list of reimbursement medicinal products and are envisaged for treating diseases that conform to the diagnoses referred to in Annex 1 to Regulation 899 are reimbursed for in the framework of the general reimbursement mechanism for medicinal products. The list

of reimbursement medicinal products that is compiled by the National Health Service, in accordance with the basic principles set out in Para 6 of Regulation 899, consists of three parts: List A, List B and List C. In accordance with the criteria referred to in Chapter VI of Regulation No. 899, such medicinal products and medicinal devices, the cost of which for treating one patient exceeds 3000 lats per year, are included on List C.

The costs of purchasing reimbursement medicinal products included on List C are reimbursed in the amount of 100 per cent, since these medicinal products are to be used in cases of severe, life-threatening diseases. This finding indirectly follows from Para 1 of Section 4 in Regulation 899, as well as Annex 1.

All those persons, with regard to whom a decision by a doctors' council, referred to in Section 67 of Regulation No. 899, has been adopted and the provisions regarding prescribing this medicinal product have been met, are eligible to claim reimbursement of the costs of purchasing medicinal product *Mabthera* included on List C. If the State authority, upon receiving the decision by the doctors' council, establishes that the number of patients defined in the decisions on including medicinal products or medicinal devices on List C has not been reached yet, it adopts a decision favourable to a person – on full reimbursement of the medicinal product indicated in the decision by the doctors' council. Whereas, if upon receiving the decision by the doctors' council the institution establishes that the number of patients defined in the decision on including medicinal products or medicinal devices on List C has been reached already, then it adopts a decision unfavourable for the person and refuses reimbursing the expenditure of purchasing the medicinal product.

The participants of the case, as well as persons summoned in this case, hold a similar opinion that all those persons, with regard to whom a decision by a doctors' council in compliance with legal acts has been adopted and the provisions for prescribing medicinal products or medicinal devices included on List C have been met, are in similar and according to particular criteria comparable circumstances.

The Health Payment Centre has recognised with regard to the Applicant both that a doctors' council has adopted a decision compliant with legal acts, and also that all conditions for prescribing medicinal product *Mabthera* included on List C have

been met. However, at the same time, i.e., after receiving the decision by the doctors' council, the institution also established that the number of patients defined in the decisions on including medicinal products or medicinal devices on List C had been reached and adopted a decision unfavourable for a person – on refusing to reimburse the expenditure of purchasing the medicinal product (*see Case Materials, pp. 92, 93 and 95*).

The Constitutional Court notes that in deciding on the issue, whether persons are under similar and comparable circumstances, the most decisive factors are, whether a decision by a doctors' council, referred to in Section 67 of Regulation 899 has been adopted and whether the requirements for prescribing the medicinal product have been met. If both these requirements have been met then, irrespectively of the fact whether the decision adopted by the institution regarding reimbursement of expenditure for purchasing medicinal products included on List C is favourable or unfavourable for a person, all these persons are under similar and comparable circumstances.

Hence, the Applicant is under similar and comparable circumstances with other persons – patients, with regard to whom a decision on reimbursing the expenditure of purchasing medicinal product *Mabthera* included on List C has been adopted.

11. The Constitutional Court has recognised that it is not always possible to assess the constitutionality of a concrete restriction upon fundamental rights only from the vantage point of the first sentence in Article 91 of the Satversme. It must be taken into consideration that the principle of equality, established in the first sentence of Article 91 of the Satversme, most frequently is to be applied together with other fundamental rights. In establishing, whether legal norms are not incompatible with the principle of equality, the field of law that they belong to must be taken into consideration. The nature of contested norms, links with other norms of the Satversme and place in the system of fundamental rights inevitably influence the legislator's discretion and, thus, also the scope of review exercised by the Constitutional Court

(*see Judgement of 8 November 2006 by the Constitutional Court in Case No. 2006-04-01, Para 15).*

In a legal situation similar to the case under review, the Constitutional Court has recognised that a legal norm must be assessed in interconnection with a person's right to health protection (*see, for example, Judgement of 29 December 2008 by the Constitutional Court in Case No. 2008-37-03, Para 11).* The Cabinet of Ministers and all summoned persons in the case are also of the same opinion that the contested norm should be assessed in interconnection with a person's right to health protection.

11.1. On the constitutional level the right to health protection is consolidated 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 also noted that this norm imposes an obligation upon the State to protect every person's right to take care of his or her health condition, as well as to abstain from actions that would hinder a person in exercising this right. Article 111 of the Satversme does not impose an obligation upon the State to ensure for everyone the highest possible level of health; however the State's obligation, in particular instances and on the level that is closely linked with the economic possibilities of the State, to implement measures for protecting human health follows from the provisions of this Article. The State's obligation to implement measures that are necessary for the protection of human health, *inter alia*, ensuring existence and accessibility of health care services and medicinal products follows from the right to health (*see, for example, Judgement of 22 October 2002 by the Constitutional Court in Case No. 2002-04-03, Para 1 of the Findings, and Judgement of 29 December 2008 in Case No. 2008-37-03, Para 11).*

Simultaneously, the obligation to ensure accessibility of medicinal products must be qualified as the obligation to ensure fundamental rights and as such may depend upon the recourses at the State's disposal.

The rapid development of contemporary medicine and science has resulted in extensive range of medicinal products and medicinal devices intended for treating various diseases. However, the State has limited resources and it cannot pay for all medicinal products, medicinal devices and treatment needed by every inhabitant. The

granting of resources to one group of patients at the same time means that these resources are denied to another group of patients.

The State must make an effort to use the available resources in such a way as to allow as many persons as possible to benefit from them. If resources are limited, then a mechanism ensuring optimum use of them is required. The State has the obligation to ensure effective use of resources and achieve fair balance in the distribution of financial resources allocated for health care, taking into consideration both the need of some patients to receive expensive health care services, as well as the general necessity to ensure accessibility of health care to as large part of society as possible.

Therefore, in fact, every state has to face the difficult task of allocating resources and, thus, decide, to whom, under what circumstances and what kind of treatment will be paid for (*see Judgement of 29 December 2008 by the Constitutional Court in Case No. 2008-37-03, Para 12).*

The State has the obligation not only to establish a legally regulated procedure, in which person can claim reimbursement for medicinal products, but also to establish a procedure, in which a person may contest a decision unfavourable to him or her. Likewise, in creating the aforementioned procedure, the State, to the extent of its possibilities, must ensure that fundamental rights, as well as the principle of equality are complied with. However, this does not mean that all patients would always have the right to receive reimbursement medicinal products or other kinds of medical services immediately.

Thus, the State has the discretion to establish a system, compatible with the fundamental rights, where persons would have the right to receive expensive medicinal products, reimbursed by the State, within reasonable time. However, Article 111 of the Satversme does not envisage the State's obligation to ensure immediate access to all medicinal products of this type.

11.2. To assess, whether the current system ensures compliance with the principle of equality, i.e., equal treatment of all persons, who are entitled to receive reimbursement medicinal products, the Constitutional Court must examine the procedure for granting these medicinal products.

The Ministry of Health has informed that the number of persons, who within the framework of a year have the right to receive reimbursement medicinal products, is determined on the basis of estimates provided by the National Health Service. Whereas the summoned persons – *Caladrius* and Association for Supporting Leukaemia Patients – consider the criteria used by this Service to estimate the number of patients who in the following year would receive reimbursement for medicinal products included on List C as questionable.

The Constitutional Court has already recognised that it cannot re-examine the actions by the decision taker in the field, which is basically founded upon estimates regarding a probable or hypothetically possible event in the future. The decision maker enjoys the freedom of making estimates and taking decisions to the extent, for example, the basic principles of the constitutional order of the State are not violated (*see Judgement of 3 February 2012 by the Constitutional Court in Case No. 2011-11-01, Para 11.2).* Thus, neither the Constitutional Court, nor the participants in the case or the summoned persons can take the position of the responsible institution of public administration and replace the considerations it has applied by their own opinion.

It follows from the materials in the case that the National Health Service estimates the number of patients regarding the medicinal products included on List C, when they are for the first time included on the list of reimbursement medicine. Whereas the number of patients is specified (increased) every year in accordance with the actual demand, by taking into consideration the financial resources available for reimbursement medicinal products. Diverse accessible sources of information are taken into consideration when estimating the number of patients. The information provided by doctors' professional associations regarding the estimated number of patients per year is seen as very significant (*see Letter by the authorised representative of the Cabinet of Ministers of 22 May 2013 on opinion in Case No. 2012-26-03, Case Materials, p. 150, as well as Para 1-3 of Section 47 in Regulation No. 899).*

The Constitutional Court notes that the aforementioned criteria – the actual demand for medicinal products included on List C, the available financial resources, as well as information provided by doctors' professional associations – cannot be recognised as being chosen arbitrarily. They are reasonably connected with the aim –

to ensure to patients the right to be reimbursed for the expenditure of purchasing medicinal products included on List C in due time.

The point made my *Caladrius* that the number of those patients, to whom in the following year the expenditure for purchasing medicinal product *Mabthera* will be reimbursed should coincide with the number of patients to who the Diagnosis has been established. I.e., within the system of reimbursement medicinal products, comparatively many medicinal products for treating the particular disease are available, and depending upon, for example, a patient's response to other medicinal products, the stage or progress of the disease, a decision to prescribe specifically the medicinal product *Mabthera* can be adopted *[see Decisions by the State Agency of Medicines Prices of 20 December 2007 No. 925 "On Including Roche Latvija, Ltd. (Reg. No. 40003731032, G. Astras iela 8b, Riga, LV–1082) medicinal product Mabthera concentrate for solution for infusions 10 mg/ml-50ml No. 1, Mabthera concentrate for solution for infusions 10 mg/ml-10ml No. 2 on the List of Reimbursement Medicinal products", Case Materials, pp. 69 – 71]*. Moreover, medicinal product *Mabthera* may be needed not only by patients with established Diagnosis, but also by patients with other diagnoses, referred to in Annex 1 to Regulation No. 899 *(see Letter by the authorised representative of the Cabinet of Ministers of 22 May 2013 on opinion in Case No. 2012-26-03, Case Materials, p. 150).*

11.3. Information obtained while preparing the case allows concluding that the State fulfils its obligation to ensure to patients access to expensive reimbursement medicinal products. This is proven by the number of patients, who have been reimbursed for medicinal products included on list C: in 2009 – 303 patients; in 2010 – 385 patients; in 2011 – 389 patients, and in 2012 – 485. Whereas in 2013 it is planned to grant reimbursement for medicinal products included on List C to 683 patients. Likewise, the constantly increasing amount of financial resources allocated and used for reimbursing for medicinal products included on List C also serves as a proof to it: in 2008 3 187 691 lats were spent for this purpose; in 2010 – 3 768 386 lats, in 2011 – 4 401 228 lats, but in 2012 – 5 429 456 lats. Whereas in 2013, it is planned to spend

8 874 330 lats for this purpose (*see Letter of 22 March 2013 by the Ministry of Health No. 01-15/1252, Case Materials, pp. 56 and 58).*

Moreover, also in cases, when the resources allocated in the State budget for reimbursing for the medicinal products included on List C have already been used, the Ministry of Health retains the obligation to find additional resources within reasonable time. The Ministry of Health notes that in those cases where the resources allocated in the State budget for reimbursing for medicinal products have been already spent this obligation follows from the task of the Ministry defined in Paragraph 5.3.2 of Regulation No. 286 adopted by the Cabinet of Ministers on 13 April 2004 "Regulation of the Ministry of Health" – to coordinate, analyse and submit proposals regarding development of the system of reimbursement medicinal products and rational use of the State budget resources for medicinal products. The Ministry of Health also prepares requests for financial resources and submits them according to the procedure established by the law "On Budget and Financial Management (*see Letter of 26 April 2013 by the Ministry of Health No. 01-15/1757, Case Materials p. 140).*

Thus, a system has been created, which imposes an obligation upon the Ministry of Health to find financial resources that are necessary to ensure timely reimbursement for medicinal products included on List C, *inter alia, Mabthera*.

12. All patients, with regard to whom a decision by a doctors' council has been adopted complying with regulatory enactments and the requirements regarding prescribing medicinal products included on List C, have the right to receive reimbursement for purchasing medicinal products. However, the contested norm *expressis verbis* envisages a provision regarding reimbursement for the expenditure of purchasing medicinal products. I.e., the granting of reimbursement for the purchase of medicinal products depends on the fact, whether the number of patients defined in the decision by the responsible institution of public administration – the Centre of Health Economics – on including medicinal products or medicinal devices on List C has been reached.

The participants of the case, as well as summoned persons hold the same opinion – that the contested norm envisages differential treatment of patients. I.e., the

contested norm is not applied to part of patients, and the responsible institution of public administration – the Health Payment Centre – immediately after receiving the decision by doctors' council adopts a decisions favourable to the patient – on full reimbursement of expenditure for purchasing medicinal product. Whereas if the institution, upon receiving the decision by the doctors' council, establishes that the resources envisaged for reimbursing the expenditure for purchasing medicinal products have been spent already, some patients are totally denied the right to receive reimbursement of expenditure for purchasing medicinal products.

Thus, allegedly the differential treatment caused by the contested norm manifests itself also as a decision, final and unconditional, adopted by applying the contested norm, to refuse reimbursement of expenditure for purchasing medicinal products included on List C to a certain group of patients.

12.1. The Constitutional Court has repeatedly recognised that a legal norm cannot be understood outside the practice of its application and the legal system, where it functions (*see, for example, Judgement of 23 November 2006 in Case No. 2006-03-0106, Para 24.5, and Judgement of 6 June 2012 in Case No. 2011-21-01, Para 8.3).*

Therefore, first and foremost, the legal consequences of applying the contested norm, also with regard to the Applicant, must be established.

With regard to the application of the contested norm, the Ministry of Health notes that all decisions by doctors' councils prepared by the medical institutions that it receives are examined in the order of receipt and registered at the National Health Service. If a person, on the basis of the contested norm, is refused reimbursement for medicinal product, but with the decision by the National Health Service on including medicinal products on List C, the number of persons to whom the expenditure for purchasing medicinal products is to be reimbursed, then the Service prepares a favourable decision – on granting reimbursement for the medicinal product. The addressee of the decision is the person, who needs reimbursement for the medicinal product, and the medicinal institution, which forwarded the decision by the doctors' council, is also informed about the adopted decision.

Prior to adopting a favourable decision, i.e., decision on reimbursing for medicinal product included on List C, the National Health Service sends an

informative letter to the respective medical institutions, which had forwarded the decisions by doctors' councils, requesting to provide information whether reimbursement of the respective medicinal product is still relevant for the persons and whether the decisions by doctors' councils do not require amendments. If the reimbursement for the medicinal product is still relevant and there is no need to amend the decisions by doctors' councils, the National Health Service adopts a favourable decision, i.e., a decision on reimbursing for medicinal products to the respective persons. Whereas, if there is a need to amend the decision by doctors' council, for example, to increase or decrease doses of the medicinal product, the National Health Service waits for a new decision by the doctors' council of the medical institution, on the basis of which a decision favourable to a person is adopted, i.e., a decision on granting reimbursement for medicinal product included on List C (*see Letter of 26 April 2013 by the Ministry of Health No. 01-15/1757, Case Materials, pp. 140 and 141)*.

12.2. The doctors' council of the limited liability company "Riga East Clinical University Hospital" on 27 May 2011 adopted a decision, noting that the Patient had been set the Diagnosis and that medicinal product *Mabthera* should be used for treatment, and that the Applicant needed four treatment courses in total: *Mabthera* 500 mg/vial – four vials – and *Mabthera* 100 mg/vial – 12 vials.

The decision of 27 May 2011 by the doctors' council was forwarded to the Health Payment Centre, which on 11 July 2011 adopted Decision No. 5.2/1.1-16/1414 (hereinafter – Decision of 11 July 2011). The contested norm was used, among other, to substantiate this administrative act, and it refused reimbursing to Applicant the medicinal product *Mabthera*. The Decision of 11 July 2011 was adopted with a restricting provision – a disclaimer of revoking, which envisaged: if a decision is adopted on increasing the number of patients, who are entitled to reimbursement for medicinal product *Mabthera*, then the Health Payment Centre would repeatedly examine the Applicant's request regarding reimbursement for this medicinal product (*see Case Materials, pp. 92 and 93*).

Approximately a month later – on 4 August 2011 – the aforementioned doctors' council adopted a new decision, indicating that the Applicant needed only three *Mabthera* courses.

This decision by the doctors' council was sent to the Health Payment Centre, which on 12 August 2011 adopted Decision No.5.2/1.1-16/1675, by which Decisions of 11 July 2011 was revoked and the Applicant was granted reimbursement for purchasing the medicinal product *Mabthera*, in accordance with the doses and quantity of the medicinal product indicated in the decision of 4 August 2011 by the doctors' council (*see Case Materials pp. 94 and 95*).

The Health Payment Centre was able to adopt Decision of 12 August 2011 No. 5.2/1.1-16/1675 because on 5 August 2011 the Centre for Health Economics had adopted Decision No. 410 and had increased by 33 the number of those patients, who had had Diagnosis C82 and C83 established and who in 2011 were entitled to reimbursement for medicinal product *Mabthera [see excerpt from Decision of 5 August 2011 by the Centre for Health Economy No. 410 "On the number of patients of Roche Latvija, Ltd. (Reg. No. 40003731032, G. Astras iela 8B, Riga, LV–1082) medicinal product Mabthera concentrate for solution for infusions 10 mg/ml-10ml No. 2 and Mabthera concentrate for solution for infusions 10 mg/ml-50ml No. 1 in the system of reimbursement of expenditure for purchasing medicinal products. Latvijas Vēstnesis, 2011. gada 10. augusts, Nr.124]*.

It follows from the above-mentioned that the responsible institutions of public administration had been able to ensure the necessary financial resources within a month to ensure that the Applicant would receive reimbursement of expenditure for purchasing medicinal product *Mabthera* in the amount that he needed.

Thus, the contested norm was applied to the Applicant in a way that the granting of reimbursement for medicinal product *Mabthera* substantially was not refused, but postponed for approximately a month.

12.3. The information provided by the Ministry of Health shows that, on the basis of the contested norm, in 2009 – 2012 268 persons were refused reimbursement of medicinal products included on List C, *inter alia*, in the period from 29 April 2009 to 11 July 2011 the Applicant and 43 more patients were refused reimbursement for

medicinal product *Mabthera*. All the aforementioned 268 persons received this compensation after the National Health Service had amended the decisions on including the particular medicinal products on the list of reimbursement medicinal products, increasing the number of those patients, who received reimbursement for medicinal products from the State budget resources allocated in the particular year for reimbursement or from the resources allocated by the registration holder (owner) or its authorised representative, a wholesaler of medicinal products or its authorised representative (*see Letter of 22 March 2013 by the Ministry of Health No. 01-15/1252, Case Materials p. 56).*

If a doctors' council has adopted a decision that a patient must use medicinal product *Mabthera,* then on average 26 days pass until the day when the National Health Service adopts a favourable decision – on reimbursing expenditure for purchasing the medicinal product (*see Letter of 26 April 2013 by the Ministry of Health No. 01-15/1757, Case Materials, p. 140).*

Whereas in the period prior to 27 July 2011, on average 60 days passed from the day a doctors' council had adopted the decision that a patient must use the medicinal product *Mabthera* (if the institution initially adopted a decision unfavourable for a person, i.e., refused to reimburse medicinal product) until the day when the institution adopted a decision favourable for the person, i.e., a decision on granting reimbursement. In the Applicant's case this period was 77 days, of which approximately a half (37 days) passed from the day when the doctors' council adopted the decision until the day the Health Payment Centre received this decision.

If the initial decision is unfavourable for a person, then on average 40 days pass until the day, when the institution adopts a decision favourable for the person – on granting reimbursement *(see the report prepared by the National Health Centre, p. 142*).

The fact that during the last two years – since 27 July 2011 – the National Health Centre has not applied the contested norm to any patient, who needed the medicinal product *Mabthera* and has not adopted a decision to refuse reimbursement for this medicinal product should be underscored in particular (*see Letter of 30 April 2013 by the National Health Service No.03.4-04.1-22/4353, Case Materials p. 146).*

In assessing the period of time when a person should start using the medicinal product *Mabthera* after the Diagnosis has been established, the Ministry of Health points to the following consideration. I.e., in the data of available clinical studies that the National Health Service has used to adopt the decision on including the medicinal product *Mabthera* on the list of reimbursement medicinal products, no reference can be found regarding the period, during which patients with the Diagnosis should mandatorily start the treatment. However, in the majority of cases the estimated life expectancy – the life expectancy of five years oscillates within the limits of 26 to 75 per cent – can be used as relative substantiation for the patient's condition and the conditional prognosis. In the case of the Diagnosis, the prognostic risk factors are said to be, first of all, linked to the patient's age, the stage of the disease and the patient's general condition of health (*see Letter of 26 April 2013 by the Ministry of Health No. 01-15/1757, Case Materials p. 140).*

Thus, the contested norm with regard to other patients, who had the right to claim reimbursement for expenditure of purchasing the medicinal product *Mabthera* was, essentially, applied in a way that the reimbursement was not refused, but only postponed.

13. Both the Applicant Court and the Cabinet of Ministers, as well as summoned persons in the case take as the basis an erroneous assumption regarding the contested norm, since they do not take into consideration the actual legal consequences of its application. I.e., the contested norm, interpreted in interconnection with the State's obligation to ensure to persons the right to access expensive reimbursement medicinal products, has not caused such consequences that the Applicant or other patients had not received reimbursement for the expenditure for purchasing the medicinal product *Mabthera.*

Quite to the contrary – the practice of responsible institutions of public administration in applying the contested norm shows that all persons, with regard to whom the decision by doctors' council referred to in Section 67 of Regulation No. 899 has been adopted and the provisions on prescribing medicinal products have been met,

have received reimbursement for expenditure of purchasing medicinal product *Mabthera* in the amount they needed.

Thus, the Constitutional Court does not see differential treatment of persons, with regard to whom the Health Payment Centre already initially adopted a favourable decision – on reimbursing the expenditure for purchasing medicinal product, and of persons, with regard to whom such favourable decision was adopted within a reasonable period of time.

Hence, the contested norm complies with the first sentence of Article 91 of the Satversme.

14. The obligation of an institution that adopts a legal norm to ensure that fundamental rights are effectively protected, observed and ensured cannot be regarded as fulfilled with the adoption or coming into force of the respective legal regulation. The institution that adopts a legal norm must *ex officio*, to the extent possible, monitor also after the legal norm has entered into force, whether in the practice of applying law this norm, indeed, effectively fulfils its task. If it is established that in the practice of applying law this norm does not function, it must be improved. The Constitutional Court has repeatedly noted that the institution that adopts a legal norm has the obligation, after a certain period of time, to re-consider, whether the respective legal regulation continues to be effective, appropriate and necessary and whether it should not be improved in any way (*see, for example, Judgement of 11 November 2005 by the Constitutional Court in Case No. 2005-08-01, Para 9.5, and Judgement of 6 June 2012 in Case No. 2011-21-01, Para 9).*

The obligation of the state power to abide in its actions by the basic principles of a judicial state, *inter alia*, the principle of legal certainty, follows from the concept of a democratic republic enshrined in Article 1 of the Satversme (*see, for example, Judgement of 19 June 2010 by the Constitutional Court in Case No. 2010-02-01, Para 4).* Whereas the demand that a legal norm, which establishes restrictions upon a person's fundamental rights, must be clear and as precise as possible follows from the principle of legal certainty (*see Judgement of 20 December 2010 by the Constitutional Court in Case No. 2010-44-01, Para 11).* The institution that adopts a legal norm has

the obligation to see to it that a legal norm is worded as unambiguously as to allow its correct interpretation and application, and an individual should be able to understand the legal consequences of its application (*see Judgement of 19 June 2010 by the Constitutional Court in Case No. 2010-02-01, Para 9.4.2, and Judgement of 11 May 2011 in Case No. 2010-55-0106, Para 13.1).*

Hence, the Cabinet of Ministers has the obligation to consider *de lege ferenda*, whether the contested norm should not be amended, so that its content would as accurately as possible coincide with the practice of its application.

The Substantive Part

Pursuant to Section 30 – 32 of the Constitutional Court Law the Constitutional Court

held:

to recognise Para 3 of Section 67^1 of the Cabinet of Ministers Regulation of 31 October 2006 No. 899 "Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment" with the first sentence of Article 91 of the Satversme of the Republic of Latvia

The Judgement is final and not subject to appeal.

The Judgement enters into force on the day it is published.

Chairperson of the court sitting A. Branta