THE CONSTITUTIONAL COURT OF THE REPUBLIC OF LATVIA

JUDGEMENT
ON BEHALF OF THE REPUBLIC OF LATVIA
in Case No. 2012-14-03
9 April 2013, Riga

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

having regard to the application submitted by twenty members of the *Saeima* of the Republic of Latvia – Vitālijs Orlovs, Sergejs Potapkins, Boriss Cilevičs, Igors Zujevs, Andrejs Klementjevs, Marjana Ivanova-Jevsejeva, Valērijs Agešins, Ivans Ribakovs, Dmitrijs Rodionovs, Sergejs Mirskis, Viktors Jakovļevs, Ivars Zariņš, Ivans Klementjevs, Jānis Tutins, Aleksandrs Sakovskis, Igors Meļņikovs, Mihails Zemļinskis, Sergejs Dolgopolovs, Jānis Urbanovičs and Raimonds Rubiks (hereinafter – the Applicant),

with the participation of the Applicant's authorised representative Eduards Ilkvids and

the authorised representative of the institution, which issued the contested act, the Cabinet of Ministers of the Republic of Latvia, – Raimonds Osis,

and the Secretary of the court sitting Elīna Kursiša,

on the basis of Article 85 of the *Satversme* of the Republic of Latvia, Para 3 of Section 16 and Para 3 of Section 17(1) of the Constitutional Court Law,

in Riga, on 5 and 12 March 2013 examined in an open court sitting the case

"**On Compliance of Para 84[1] and Para 89 of 31 October 2006 Cabinet of Ministers Regulation No. 899 "Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment" with Article 91 and Article 111 of the Satversme of the Republic of Latvia."**

The Facts

1. On 31 October 2006 the Cabinet of Ministers, pursuant to Para 20 of Section 5 in the Pharmaceutical Law issued 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).

1.1. Para 84[1] and Para 89 of Regulation No. 899 (hereinafter also – the contested norms) in the wording that was in effect at the moment of submitting the application, provided:

"84.[1] If the patient in the framework of reimbursement procedure previously has not received medicinal products or medicinal devices included in list A envisaged for the concrete diagnosis, the physician shall prescribe on the special form for prescription the common name of the medicinal product or medicinal device intended for this diagnosis."

"89. If a physician, in writing a prescription for reimbursable medicinal products, has used the common name of a medicinal product, the duty of a pharmacist is to dispense the cheapest reimbursable medicinal products, which conform with this name, the prescribed pharmaceutical form and strength, but if the list of reimbursement medicinal products contains two or more medicinal products with the lowest basic price for reimbursement – the medicinal product, which has been granted the status of the cheapest medicinal product by the National Health Service. If a physician, in writing a prescription for reimbursable medicinal devices, has used the

common name of a medicinal device, the duty of a pharmacist is to dispense the cheapest reimbursable medicinal devices, which conform with this name and the type of usage, but if the list of reimbursement medicinal devices contains two or more medicinal devices with the lowest basic price for reimbursement – the medicinal device, which has been granted the status of the cheapest medicinal device by the National Health Service. It is prohibited within the framework of reimbursement procedure to dispense medicinal products or medicinal devices that do no comply with these terms."

1.2. On 9 October 20102 the Cabinet of Ministers adopted Regulation No. 701 "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"", which, *inter alia*, amended Para 89 of Regulation No. 899, expressing its third sentence in the following wording:

"If the pharmacy has submitted to Health Inspectorate information referred to in Para 91 of this Regulation on the inaccessibility of reference medicinal product or medicinal device or the cheapest medicinal product and medicinal devices of common name available within the system of reimbursement, the pharmacist may dispense to the patient the next cheapest medicinal product or medicinal device."

2. The Applicant – **twenty members of the 11th *Saeima* of the Republic of Latvia–** that the contested norms are incompatible with Article 91 and Article 11 of the *Satversme* of the Republic of Latvia (hereinafter – the *Satversme).*

The Applicant notes that all patients, irrespectively of the time when the diagnosis has been set, are in similar and comparable circumstances. If patients have the same diagnosis, they need the same reimbursement medicinal products. After coming into force of the contested norms, the patients allegedly have been divided into two groups, for which different procedures for reimbursing the expenditure of acquisition of medicinal products have been set.

Those patients, who previously received reimbursement medicines envisaged for the particular diagnosis, retain the right to receive the medicines of specific name,

indicated in the prescription, if necessary, paying the difference between the price of the selected and cheaper reference medicines. Whereas the second group of patients, which previously had not received reimbursed medicines in the framework of reimbursement system, can receive those reference medicinal products, the status of cheapest medicinal goods of which has been determined by the National Health Service. Thus, the contested norms allegedly envisage differential treatment of persons, who are in similar and comparable circumstances.

The contested norms have a legitimate aim – decreasing the expenditure for acquisition of medicines. However, the patients' right to choose other medicinal products instead of the cheapest reference medicinal products should not be restricted because of this aim.

The measures envisages by the contested norms allegedly are not suitable for reaching the legitimate aim. If a patient wants to purchase medicines, which have not been granted the status of cheapest reference medicines or if the cheapest reference medicines are not available at the pharmacy, then the contested norms deny the patient the possibility to receive the medicines that he or she needs or makes him or her purchase these paying a full price. Thus the accessibility of medicines and saving of patients' resources is not ensured and the legitimate aim of the contested norms is not reached.

Allegedly, the legitimate aim of the contested norms can be reached by measures that are less restrictive to patients' rights, for example, by establishing an obligation for the pharmacists to offer to the patient the cheapest reference medicines, but allowing him or her to choose, which medicinal products to purchase. In such a case the patients could pay the price difference of the chosen and cheapest reference medicines, and the State would not incur additional expenses. Thus, compliance with the principle of equality would be ensured and the rights of all patients to purchase the medicines that they need would be protected.

The benefit to society is said to be smaller than the damage inflicted upon an individual's right, since the interests of the whole of society are not balanced.

The Applicant's representative – Eduards Ikvilds – at the court sitting upheld the claim and requested recognising the contested norms as being incompatible with the *Satversme*.

3. The institution, which has adopted the contested norms, **– the Cabinet of Ministers of the Republic of Latvia** (hereinafter – the Cabinet) – does not uphold the Applicant's opinion and holds that the contested norms comply with the norms of a higher legal force.

The Cabinet notes that the totality of measures of medical assistance guaranteed by the State comprises also reimbursement of the expenditure of acquiring medicinal products and medicinal devices from the State budget. In response to the development of the pharmaceutical market and changing needs of the inhabitants, the procedure for reimbursing the expenditure for acquiring medicines and medicinal devices has been amended and improved a number of times, to eliminate the identified problems and shortcomings. Before the contested norms had come into effect, a situation could be observed, where the producers and distributors of medicines had tried to make physicians interested in prescribing particular medicines, thus distorting competition in the medicines market. The contested norms had been adopted with the aim of promoting competition between producers and distributors of medicines, as the result of which the prices of reimbursement medicines would decrease. Thus, the contested norms ensure saving of patients' and the State's resources and channelling recourses to satisfy other needs within the system of reimbursement.

The contested norms allegedly do not envisage differential treatment of different groups of patients. They only differentiate the procedure, in which medical practitioners prescribe and the pharmacists dispense medicines within the framework of reimbursement system. The procedure for dispensing medicines and reimbursing the expenditure of acquisition is based upon the stage of medicines' use – first time use or continuous use. Thus, the contested norms allegedly differentiate the procedure for dispensing medicines in different stages of their use.

The Cabinet holds that the differential treatment is allowed and is justified by two legitimate aims. One of these is reducing the costs of purchasing medicines for inhabitants, whereas the other – saving the State budget resources, to make rational use of them and to ensure the availability of reimbursement medicines to as large number of patients as possible. The mandatory requirement regarding prescribing and dispensing the cheapest medicines to patients within the framework of the State

reimbursement system is one of the measures, which stimulates competition among producers and distributors of medicines and decreases the prices of medicines.

The contested norms are said to reach their legitimate aim, since they foster the competition among producers and distributors of medicines and decrease the price of medicines. According to the data aggregated by the National Health Service, following the adoption of the contested norms the producers and distributors of medicines had offered to reduce the prices of many reimbursement medicines.

The alternative measure offered by the Applicant – permission to patients to purchase also more expensive medicines, paying the price difference of the selected and cheaper reimbursement medicines, – would not ensure reaching the legitimate aim in the same quality. In this case the competition among producers and suppliers of medicines would decrease, the prices of medicines would grow, and the savings of the State budget resources allocated for reimbursing the expenditure of acquisition of medicines and the possibility to channel these resources for satisfying other needs within the system of reimbursement medicinal products would decrease. Thus, allegedly it is impossible to reach the legitimate aim of the contested norms with less restrictive measures.

The Cabinet notes that the as regards patients, who have received reimbursement medicines already previously, the positive effect of their use has been confirmed. Therefore it is useful for them to continue the treatment with the particular medicines. As regards those patients, who receive the particular reimbursement medicines for the first time, there are no grounds to assume that the use of cheaper medicines will not bring the desirable therapeutic effect. Whereas in those cases, when the cheapest medicine does not bring the desirable effect, the physician has the right to prescribe other reimbursement medicines with the next lowest price within the framework of the common name. In the presence of such procedure for prescribing and dispensing medicines society as a whole benefits from decreasing prices of the medicines and the State does not need to narrow the range of reimbursement medicines or decrease the amount of reimbursement. Therefore the benefit to society exceeds the harm inflicted upon the interests of some individuals.

The Cabinet noted that on 9 October 2010 amendments were made to Para 89 of Regulation 899. Thus, the possible problems of inaccessibility of cheapest reimbursement medicines in pharmacies have been eliminated. In accordance with these amendments the patients have the right to receive the cheapest reimbursement medicines available in pharmacies also if the cheapest medicine as defined by the National Health Service is not available at the pharmacy.

During the court sitting the representative of the Cabinet – Raimonds Osis, the Head of the Legal Department of the Ministry of Health – in addition to the what had been stated previously noted that the Cabinet, by adopting the contested norms, had not interfered with the process of treatment. Physicians still have the right, within the limits of their professional discretion, to prescribe to a patient not only medicines of common name, but also other medicines that would be best suited for reaching the desirable therapeutic effect, to the extent such action has objective medical grounds. Therefore the Cabinet had selected more lenient measures that ensured a balance between facilitation of competition and patients' interests.

4. The summoned person – **the Ombudsman of the Republic of Latvia** (hereinafter – the Ombudsman) – notes that the compliance of the contested norms with Article 91 and Article 111 of the *Satversme* had ben examined in the Ombudsman's inspection case No. 2012-44-26K, initiated on the basis of an application by Vitālijs Orlovs regarding possible violations of the reimbursement medicines procedure.

The opinion concluded that patients, to whom reimbursement medicines have been prescribed before and after 1 January 2012, constitute groups of persons, who are in similar and comparable circumstances. The common uniting factor for both groups is the fact that the patients have the right, within the framework of procedure for compensation, to receive State reimbursed medicines envisaged for the particular diagnosis.

The contested norms allegedly envisage differential treatment of the aforementioned groups of persons, depending upon the time of initiating therapy. The differential treatment has a legitimate aim – to ensure the accessibility of as cheap medicines as possible to as large number of people as possible. However, the

differential treatment is said to be incompatible with the principle of proportionality, since the legitimate aim of the contested norms can be reached by measures that are less restrictive to a person's rights, for example, by ensuring the possibility to all patients, who receive reimbursement medicines, to choose, whether to receive the cheapest reference medicines or whether to choose medicines that are more expensive or better suited to the status of health, and to pay the price difference. That would not cause additional expenditure in the budget, since the State already now reimburses the expenditure of purchasing the cheapest medicines.

Article 11 of the *Satversme* establishes the obligation of the State to protect public health. The Ombudsman is of the opinion that the procedure for prescribing and dispensing medicines set out in the contested norms cannot fully ensure accessibility of medicines. Cases have been identified when pharmacies were unable to ensure purchase of cheapest reimbursement medicines. A situation like this is to be assessed as a violation of the right to health care and is incompatible with Article 111 of the Satversme.

Thus, the contested norms are incompatible with the principle of equality established by Article 91 of the Satversme, and also violate the right to health care guaranteed by Article 111 of the Satversme.

This position was upheld also during the court sitting by the Head of the Division of Equal Treatment Šarlote Bērziņa.

5. The summoned person – **the Ministry of Health** – notes that before the contested norms were implemented, a negative trend was observed in the market that the amount of resources used for purchasing original (patented) medicines was increasing. Physicians had indicated in prescriptions concrete names of medicines, and patients were not informed about the possibility to purchase cheaper medicines with equal medical efficacy. Whereas the producers, to avoid competition, were offering interchangeable medicines for equally high prices. This situation pointed to lack of competition in medicines market, and as the result both the patients and the State were overpaying for the acquisition of medicines.

The Ministry of Health also notes that an increase in the number of patients in the amount of 3 – 5 per cent is observed annually. Within the limits of the current budget

possibilities the State is unable to ensure appropriate increase in the funding for reimbursement medicines. To prevent the need to decrease the amounts of reimbursement of expenditure for acquisition of medicines or the range of reimbursement medicines, the most lenient mechanism is to increase the competition in the medicines market, which also leads to the decreasing prices of reimbursement medicines.

The contested norms allegedly do not divide patients into particular groups, but establish the procedure for reimbursing expenditure of acquisition of medicines, depending upon the stage and efficacy of medicine use, which, essentially, is similar for all patients. When patients receive for the first time reimbursement medicines envisaged for a particular diagnosis, there are no reasons to prefer medicines of a particular producer, and, thus, the price of medicines is the only objective criterion. If medicine turns out to be ineffective, it can be replaced. Whereas those patients, who already have previously received particular reimbursement medicine, can continue using it, if its therapeutic efficacy has been confirmed.

The Ministry of Health admits that the application of the contested norms could have led to limited availability of medicines in pharmacies. However, the amendments to Para 89 of Regulation No. 899 have eliminated this problem.

At the court sitting the representative of the Ministry of Health, State Secretary Rinalds Muciņš noted in addition to what had been stated previously that only such medicines, which have equivalent alternatives with equal medical efficacy, are included in list A. The equivalence of these medicines has been proven, since no medicine enters the market without a registration procedure recognised by the State. The obligation of the State to ensure availability of medicines, *inter alia*, by reimbursing the expenditure of acquiring these, follows from Article 111 of the *Satversme*, however it does not comprise the State's obligation to ensure medicines most suited to the subjective wishes of each patient. Thus, the State within the limits of its possibilities ensures minimum support to all patients.

6. The summoned person – **the National Health Service** – notes that the contested norms ensure effective and optimal use of the State budget resources within the framework of the reimbursement procedure, as well as decrease the co-payments

made by patients. As the result of applying the contested norms the supplier, who offers the lowest price, can reckon with greater sales of medicines, which leads to increased competition among suppliers and decreasing prices of medicines. Information aggregated by the National Health Service allegedly proves that following the implementation of the contested norms the prices of many medicines decreased.

Many of the medicines included in the list of reimbursement medicines are equal as to their efficacy, but differ as to their price. There are no significant differences between generic and original medicines as to their effectiveness and side effects, and the equal efficacy of these medicines has been proven in trials. Prescribing of cheapest medicines is extensively promoted also in other European states.

The National Health Service holds that the contested norms do not envisage differential treatment of persons, who are in similar and comparable circumstances. The contested norms are applicable to all patients; however, those persons, who have previously received particular reimbursement medicines, should be allowed to complete the course of treatment that has been started.

The application of the contested norms does not lead to decreased availability of medicines in pharmacies. Any wholesaler may experience problems in ensuring delivery of medicines, however, this is not linked with the procedure for reimbursing expenditure of acquisition of medicines. Such situations should be seen as rare exceptions, and those medicines, which are not available, are deleted from the list of reimbursement medicines. The National Health Service also noted that any problems linked with the availability of medicines had been eliminated by amendments to Regulation No.899.

However, at the court sitting the representative of the National Health Service Artūrs Pučmucāns noted that the contested norms couldn’t be examined in isolation from other norms, which envisaged exceptions to the general principle. These exceptions envisage the rights of general practitioners to prescribe other reimbursement medicines, if there are objective medical reasons for that, as well as the right of a pharmacist to dispense other medicines, if certain conditions are established. Hence, the contested norms do not restrict the availability of medicines and are compatible with the Satversme.

7. The summoned person – **the Latvian Association of General Practitioners** (hereinafter – LAGP) – notes that the selection of medicines, most appropriate as to their efficacy and price, should be left for the physicians and patients to decide, whereas the State could retain uniform amount of reimbursement for the medicines of all producers.

LAGP holds that the contested norms envisage differential treatment of two different groups of patients, depending upon the stage of using medicines – first time use or continuous use.

The contested norms may have an adverse impact upon the right to health protection, guaranteed in Article 111 of the Satversme. The application of these may lead to undesirable interruptions in the use of medicines, since reimbursement medicines are not always freely available in all pharmacies, whereas delivery or substitution by other medicines can take several days.

At the court sitting LAGP representative Pauls Princis noted that medicines produced by different producers, having one common name, could have rather different quality and impact upon a patient's health. Likewise, the same active ingredient does not guarantee identical impact of medicines, since the chemical properties of the respective active ingredient may differ. A physician needs discretion, in order to ensure the most appropriate course of treatment to every patient.

8. The summoned person – **the Latvian Association of Rural General Practitioners** (hereinafter – LARGP) – notes that the contested norms cause problems to patients, physicians and pharmacists alike.

The contested norms allegedly restrict patients' rights to the possibility to procure medicines reimbursed by the State and to coordinated and uninterrupted health care. Physicians' work is hindered, since the contested norms do not allow prescribing the most appropriate medicinal product to the patient without previous experimenting with other medicines. The contested norms also allegedly have adverse impact upon the market of medicines and medicinal devices, leaving the pharmacist in charge of selecting medicines to be dispensed to the patient.

At the court sitting LARGP representative Valērijs Valdmanis noted that the current procedure made it difficult for general practitioners to control the treatment

process of patients, since the physician was not informed about exactly which medicines were dispensed to them at the pharmacy. Identical common name of medicines does not mean that they are all equal, since medicines can have different forms, which determine they impact upon organism. The primary task of medical care is to take care of patients' health, and this should not be subject to economic considerations.

9. The summoned person – **the Latvian Pharmacists Society** (hereinafter – LPS) – considers that the contested norms envisage differential treatment of patients, depending of the time of prescribing reimbursement medicines.

The adoption of the contested norms left an adverse impact upon the accessibility of medicines to patients within the framework of reimbursement medicines system. If the supplier is unable to ensure constant availability of the particular medicine in Latvian market, it is deleted from the list of reimbursement medicines. This process is time-consuming and complicated, and during the period the patient is not receiving the medicines that he or she needs. This problem has not been completely solved with amendments to Para 89 of Regulation No. 899.

Numerous wholesalers operate in the medicines market, and pharmacies are unable to aggregate information on the availability of medicines in the market in a sufficiently fast and effective way. The contested norms and the regulation established by Regulation No. 899 complicate distribution of reimbursement medicines and medicinal devices to patients. This restricts the accessibility of health care and creates a potential threat to patients' health.

At the court sitting the representative of LPS Agnese Ritene noted that the amendments introduced to Para 89 of Regulation No. 899 did not solve the problem of accessibility of reimbursement medicines. Pharmacies are unable to aggregate information that the particular medicine is not available from all wholesalers of medicines sufficiently fast and, thus, are unable to comply with the requirement included in the contested norms – to dispense to the patient the next cheapest reimbursement medicine. Even if particular medicine is deleted from the list of reimbursement medicine, it is possible that wholesalers have not managed to ensure sufficient reserves and the next cheapest medicine will not be available either.

10. The summoned person – **the Latvian Generic Medicines Association** (hereinafter – LGMA) – expresses the opinion that the contested norms envisage differential treatment of patients, who have previously received reimbursement medicines appropriate for a particular diagnosis, and patients, who previously have not received reimbursement medicines in the framework of procedure for reimbursement. This differential treatment allegedly has no objective and reasonable grounds.

Categorisation of patients, depending upon the stage of medicines use, restricts the medical practitioners' discretion and the right to prescribe the medicines that are best suited to the patient. In some diagnosis it is important to ensure constant effectiveness of the treatment with medicines. However, the medicines with similar common name, offered by different producers, may differ as to their therapeutic efficacy. Moreover, medical practitioners have empirical experience they rely upon, when dispensing particular medicines to patients.

Application of the contested norms may lead to situations, where all the necessary medicines are not ensured to patients, because they are unavailable at pharmacies. Amendments to the list of reimbursement medicines are introduced twice per year and significantly change the demand for particular medicine. Pharmaceutical companies do not create large reserves of medicines; therefore four to six months are needed to produce the necessary amount of particular medicines. Moreover, in the production of some medicines a yearly cycle is observed. Therefore the producers of medicines cannot timely assess the demand and ensure availability of particular medicines in pharmacies.

LGMA explains that the application of the contested norms could have a negative impact upon competition in the medicines market, i.e., producers may leave it, leading to the narrowing of the range of available medicines. In such a case the effect would be absolutely contrary to the aim of the contested norms, as with the decreasing range of available medicines the prices of the medicines remaining in the market would increase.

At the court sitting the representative of LGMA Evita Jaunzeme noted that the amendments to Para 89 of Regulation No. 899, made by the Cabinet, did not solve

problems in the availability of medicines. The requirements that the pharmacist has to meet before dispensing the next cheapest medicine are allegedly so cumbersome that it is impossible to meet them within reasonable time.

The Findings

11. The Applicant requests the Constitutional Court to assess the compatibility of the contested norms with Article 91 and Article 111 of the Satversme.

The principle of legal equality, enshrined in the first sentence of Article 91 of the Satversme, predominantly should be applied together with other fundamental rights, since often a case cannot be adjudicated only on the basis of this principle. The right enshrined in Article 91 of the Satversme is "relative". It can demand equal treatment, but *per se* cannot reveal what this treatment should be like, i.e., whether it should be favourable or unfavourable. To choose one of these solutions, other considerations, which are beyond the limits of the equality concept, must be taken into consideration (*see, for example, Judgement of 11 November 2005 by the Constitutional Court in Case No. 2005-08-01, Para 5 and Para 6.1, and Judgement of 7 June 2012 in Case No. 2011-19-01, Para 8).*

Thus, in assessing the compliance of the contested norms with Article 91 of the Satversme, the content of fundamental rights included in Article 111 of the Satversme is important.

12. Article 111 of the Satversme provides: "The State shall protect human health and guarantee a basic level of medical assistance for everyone."

The Constitutional Court has recognised that the State's obligation to *respect, protect* and *ensure* a person's right to health follows from Article 111 of the Satversme. The obligation to *respect* the right to health – it means that the State must refrain from interfering with a person's rights and freedoms. It must abstain from such activities that restrict a person's possibilities to take care of his or her own health protection. The obligation to *protect* the right to health – this means that the State must protect a person from other persons interfering with his or her exercise of fundamental rights. Whereas the obligation to *ensure* the right to health means that the State must

implement concrete measures for exercise of this fundamental right (*see Judgement of 22 October 2002 by the Constitutional Court in Case No. 2002-04-03, Para 1 of the Findings, Judgement of 23 April 2004 in the Case No. 2003-15-0106, Para 6, and Judgement of 29 September 2008 in Case No. 2008-37-03, Para 12.1.2).*

An obligation of the State to ensure to everybody the highest possible level of health does not follow from this norm of the Satversme. However, the right to health comprises not only concrete *freedoms*, but also concrete *rights. Freedoms*, for example, mean that every person is free to control his or her own health. The Constitutional Court has also pointed to persons' rights to implement measures that he or she deems to be necessary to ensure their health. Whereas the *rights* must be linked with the State's obligation to create an appropriate system of health protection. Thus, the State's obligation to ensure the existence and accessibility of health care institutions, services, equipment and medicines, as well as other circumstances that influence the possibility for persons to attain the highest level of health, corresponds to the right to health (*see Judgement of 22 October 2002 by the Constitutional Court in Case No. 2002-04-03, Para 1 of the Findings, Judgement of 23 April 2004 in Case No. 2003-15-0106, Para 6, and Judgement of 29 September 2008 in Case No. 2008-37-03, Para 11).*

The Constitutional Court has recognised that the obligation of the State to ensure accessibility of medicines follows from Article 111 of the Satversme. The State cannot refuse to fulfil the economic, social and cultural rights included in the Satversme, however, the scope of implementation of these rights may depend upon the resources at the disposal of the State. Therefore it is the task of the State to allocate resources and decide, to whom, under what circumstances and what kind of treatment shall be paid for. There are no universal criteria for setting priorities in this field, therefore the State has broad discretion in deciding these issues (*see Judgement of 13 March 2001 in Case No. 2000-08-0109, the Findings, Judgement of 11 December 2006 in Case No. 2006-10-01, Para 14.2 and Para 14.3, and Judgement of 29 September 2008 in Case No. 2008-37-03, Para 12.1.2 and Para 12.1.3).*

13. The contested norms must be assessed as part of the mechanism that the State uses to fulfil its obligation to ensure accessibility of medicines. The criteria that are

used to assess the compliance of legal norm with fundamental rights may differ, depending on the fact, whether the particular norm restricts rights granted to a person or define fulfilment of the State's positive obligations (*see Judgement of 6 April 2005 by the Constitutional Court in Case No. 2004-21-01, Para 10, Judgement of 11 December 2006 in Case No. 2006-10-03, Para 16.1, and Judgement of 21 December 2009 in Case No. 2009-43-01, Para 26).*

The Constitutional Court has already noted that in assessing, whether the State has fulfilled its positive obligations, which follow from a person's fundamental rights, it must be verified, whether:

1) the legislator has implemented measures to ensure exercise of rights;
2) these measures have been implemented duly, i.e., whether persons have been ensured the possibility to ensure their rights in at least minimum amount;
3) the general principles of law, which follow from the Satversme, have been abided by (*see Judgement of 11 December 2006 by the Constitutional Court in Case No. 2006-10-03, Para 16.1).*

14. In verifying, whether the State has implemented measures for realising all fundamental rights included in Article 111 of the Satversme, it must be assessed, whether the legislator has created a system that ensures accessibility of medicines.

The legislator, fulfilling its positive obligation, which follows from Article 111 of the Satversme, to ensure accessibility of medicinal products, has adopted a number of regulatory enactments, *inter alia*, the Medical Treatment Law, the Pharmaceutical Law, law "On Doctors Working in Doctor's Practices", Law on the Rights of Patients, and other laws connected with ensuring health care. Whereas the Cabinet of Ministers, on the basis of the aforementioned laws, has issued regulations, which regulate the procedure for exercising the rights included in laws. The case does not contain a dispute, whether these regulatory enactments have created a system within the State to ensure health care and accessibility of medicinal products.

Moreover, in accordance with Para 20 of Section 5 of the Pharmaceutical Law, the Cabinet has issued Regulation No. 899, which regulates the procedure for reimbursing the expenditure for acquisition of medicines and medicinal products

envisaged for out-patient treatment. Thus, the State has taken care of the accessibility of fully or partially reimbursed medicines and medicinal products to all patients.

Thus, the legislator has created a system that ensures accessibility of medicinal products.

15. In verifying, whether all these measures have been duly implemented, i.e., whether the possibility has been ensured to persons to exercise their rights in at least minimum amount, it must be assessed, whether the system established by the legislator creates adequate accessibility of medicinal products and the impact of the contested norms upon it. A State's obligation to ensure to everybody the necessary medicines free of charge does not follow from the right to health. However, the obligation to ensure accessibility of medicines, comprises not only establishing a general system, but also the obligation to see to it that medicines were financially accessible to individual patients (*see Judgement of 29 September 2008 by the Constitutional Court in Case No. 2008-37-03, Para 12.1.1).*

Article 111 of the Satversme does not define in what way the State should take care of the accessibility of medicinal products; therefore the legislator has discretion to select the most appropriate means for fulfilling this obligation. This obligation can be fulfilled by establishing a health insurance system, by granting benefits for purchasing medicinal products, by reimbursing resources spent to purchase medicinal products or by other means. Para 20 of Section 5 of the Pharmaceutical Law, and the Regulation No. 899 adopted on its basis, have been selected by the legislator to ensure accessibility of medicines by a mechanism of reimbursement, in the framework of which patients are ensured the possibility to receive fully or partially reimbursed medicinal products.

The written reply by the Cabinet explains that several considerations have served as the basis for adopting the contested norms, *inter alia*, the need to promote competition among the producers and distributors of reimbursement medicines and medicinal devices, to decrease the inhabitants' expenditure for acquisition of medicinal products and to save the State budget resources, to use them rationally for

other purposes and to ensure the accessibility of reimbursement medicines for as large number of patients as possible (*See Case Materials, Vol.1, p. 30*).

If the competition among the producers and distributors of medicines and medicinal devices is promoted, the prices of medicines and medicinal devices decrease, thus, inhabitants have the possibility to purchased cheaper medicines, and the State budget expenditure for reimbursing expenditure for acquiring medicinal products decreases. The saved resources can be used to ensure the accessibility of reimbursement medicines and medicinal devices to as broad circle of persons as possible.

Information aggregated by the National Health Service shows that after the adoption of the contested norms a decrease in the prices of reimbursement medicines could be observed, as the result of which the State budget resources that were saved could be channelled for serving other needs of the patients within the system of reimbursement medicinal products (*see, Explanations and Aggregated Statistics by the National Health Service "On Disbursements for Reimbursement Medicinal Products according to the General Procedure in 2009-2012, Case Materials, Vol. 1, p.141 and Vol.2, p. 144).*

The Constitutional Court has recognised already before that the regulation aimed at accessibility of reimbursement medicines to as broad circle of persons as possible, under the conditions, when the State's financial possibilities are not sufficient, has a legitimate aim – to protect other persons' right to health (*see Judgement of 29 September 2008 by the Constitutional Court in Case No. 2008-37-03, Para 11.3).*

Thus, the measures aimed at decreasing the expenditure for purchasing medicinal products for patients and economising the resources of the State to ensure the accessibility of reimbursement medicinal products to as broad circle of patients as possible not only falls within the discretion granted to the Cabinet of Ministers, but even is the Cabinet's obligation. However, in interconnection with the contested norms, the impact of the procedure established by the Cabinet upon the accessibility of reimbursement medicinal products to individual patients must be assessed.

15.1. Para 84^1 of Regulation 899 envisages: "If the patient in the framework of reimbursement procedure previously has not received medicinal products or

medicinal devices included in list A envisaged for the concrete diagnosis, the physician shall prescribe on the special form for prescription the common name of the medicinal product or medicinal device intended for this diagnosis."

First of all, it must be taken into account that Regulation No. 899 regulates the procedure for reimbursing expenditure for the acquisition of medicines and medicinal devices, but no the procedure of treatment and the particular contested norm should be assessed in this context.

The Applicant's opinion that the State by the contested norms interferes with the procedure of treatment and imposes the use of concrete medicines or medicinal devices (*see Case Materials, Vol. 1, pp. 5- 6)* cannot be upheld. Regulation No. 899 regulates the procedure and the kinds of expenditure for acquisition of medicines and medicinal devices the State has undertaken to reimburse, but does not define a physician's obligation to prescribe medicinal products, which are inappropriate for treating a patient. Outside the procedure for reimbursement, the physician still has the right to prescribe medicinal product of any particular name. The Constitutional Court already noted in this Judgement that the State's obligation to ensure any medicine free of charge did not follow from the right to health.

Moreover – in a situation, where the State has undertaken to pay for the medicinal products necessary for treating particular diseases, it has the right to establish a procedure for reimbursing the expenditure of acquiring these medicinal products, *inter alia*, limiting the reimbursement to the expenditure for acquiring the cheapest reference medicinal product.

Secondly, it must be taken into consideration that the contested norm defines a physician's obligations only with regard to those patients, who have not previously received, within the system of reimbursement, medicines or medicinal devices included in A list, envisaged for the particular diagnosis. To those patients, who in the framework of reimbursement procedure have previously received particular reimbursement medicines, the physician still has the right to prescribe the same medicines of a particular name that the patient received before *(See Written Answer by the Cabinet of Ministers, Case Materials, Vol. 1, pp. 30*).

In accordance with Para 6.1 of Regulation 899, in the framework of the common name of medicines, medicines with equal therapeutic efficacy or medicinal devices

with the same kind of application are included in List A. No evidence has been submitted in the case that the interchangeable medicines with the same common name would significantly differ as to their quality or effectiveness. Otherwise, these medicines could not be included in reimbursement List A as interchangeable medicines. Thus, there are no grounds to consider that the cheapest reference medicines or medicinal devices, which are dispensed in accordance with the common name of medicines or medicinal devices indicated in the special prescription, in general will not be suitable for a patient's health care.

Moreover, the requirement established in Para 84^1 of Regulation 899 on indicating the general name of medicines or medicinal devices in the special prescription should be assessed in the interconnection with exceptions to the general procedure established in Para 84^2.

Even though all medicines and medicinal devices included in List A of reimbursement medicines have equal therapeutic effect, situations may arise, when the medicinal product because of adjuvants included in it or because of other pharmaceutical properties is not suitable for treating a particular patient. In accordance with Para 84^2 of Regulation 899, when medicines or medicinal devices do not produce the desirable therapeutic effect, the physician prescribes other medicines or medicinal devices instead of these, beginning with the cheapest price within the framework of the common name. The Cabinet notes that a physician may exercise this right both after having established that the cheapest reference medicine of common name does not produce the desirable therapeutic effect, and also in the case when reimbursement medicines or medicinal products are dispensed for the first time, if such actions are substantiated by medical considerations. However, as the representative of LARGP indicated, it is not clear how this norm will be interpreted by controlling institutions.

The issue what is to be considered as the desirable therapeutic effect and whether the particular medicines or medicinal devices reach it, is a medical, not a legal one, and as such falls with the competence of the physician, who provides treatment. Only the physician, who examines the particular patient and sets the diagnosis, can determine the necessary course of treatment, *inter alia*, assessing also, whether the cheapest reference medicinal product will produce the necessary therapeutic effect. A

physician can consider this also when prescribing reimbursement medicinal product for the first time.

Also in those cases, when the State has implemented measures aimed at saving budget resources, a physician has the obligation, pursuant to the ethics of the profession, not to prescribe particular medicines, if this does not comply with the treatment needs of his or her patient (*see Judgement of 22 April 2010 by the Court of Justice of the European Union in Case No. C-62/09, Para 35 –40).*

A physician, having established that the cheapest reference medicinal product, which, in accordance with the common name indicated in the prescription, has been dispensed at the pharmacy, is not producing or will not produce the desirable therapeutic effect, may prescribe in the framework of reimbursement procedure also other medicines or medicinal devices, starting with the cheapest price within the framework of the common name. Such actions cannot be arbitrary, they must be substantiated by medical considerations, and the substantiation, why the cheapest reference medicinal product will not produce the desirable therapeutic effect, must be indicated in the patient's file. Whereas controlling institutions, essentially, may check only, whether the physician has provided the appropriate objective substantiation and whether the physician's actions are not evidently arbitrary.

It follows from the abovementioned, that the State has undertaken to reimburse expenditure in equal amount not only for the cheapest reference medicines, but also for other, more expensive medicinal products included in List A of reimbursement medicines, insofar dispensing of such is substantiated by medical considerations.

Thus, Para 84^1 of Regulation 899 ensures persons' possibilities to exercise the fundamental rights set out in Article 111 of the Satversme.

15.2. Para 89 of Regulation Nr. 899 regulates the procedure, in which a pharmacist dispenses the reimbursement medicines or medicinal devices, as well as establishes the procedure, in which a pharmacist may dispense to a patient the next cheapest medicine or medicinal device.

The first two sentences of this paragraph establish a pharmacist's obligation to dispense the next cheapest medicine or medical devices according to the common name. Essentially, this requirement is linked with the issue, already examined in this

Judgement, abut the aims of the mechanism for promoting competition, as well as the limits of a physician's discretion. If a physician has concluded that there are no objective medical considerations proving that the cheapest reference medicine might not produce the desirable therapeutic effect, he or she takes into consideration that the patient at the pharmacy will receive the cheapest respective medicine.

The Applicant expresses the opinion that no additional expenses would be caused for the State, if the patient were to be allowed to purchase any medicinal products of the common name, paying the price difference of the selected and the cheapest reference medicinal products (*see Case Materials, Vol.1, p.12*).

This argument expressed by the Applicant should be assessed in interconnection with the essence of the mechanism for promoting competition among the producers and distributors of medicines, i.e., making the producers and distributors or medicines interested in offering medicines for the lowest price. Whereas the State and society benefit only from the price decrease that the competition leads to. Whereas by allowing any patient, within the framework of the reimbursement system, to freely select any medicinal products, also by paying additionally for the most expensive ones, it would be impossible to guarantee for the producers and wholesalers of a particular medicinal product a stable amount of sales, and they would not be interested to compete in order to acquire the status of the cheapest reference medicinal product.

Thus, the first and the second sentence of Para 89 of Regulation 899 ensure accessibility of reimbursement medicinal products at least on the minimum level.

16. The third sentence of Para 89 of Regulation No. 899, in the wording of 27 December 2011, provided: "It is prohibited within the framework of reimbursement procedure to dispense medicinal products or medicinal devices that do no comply with these terms." However, the Cabinet amended the particular norm, establishing a procedure for dispensing the next cheapest reimbursement medicinal product, in case of necessity. The wording of the norm, which is currently in force, has not been contested.

In accordance with Para 2 of Section 29(1) of the Constitutional Court Law, legal proceedings in a case may be terminated before the Judgment is pronounced, by the decision of the Constitutional Court, of the legal norm (act) has become invalid.

In construing Para 2 of Section 29 (1) of the Constitutional Court Law, it must be taken into consideration that this norm is aimed at ensuring the economy of proceeding before the Constitutional Court and that the Constitutional Court should not make judgements in cases, where the dispute no longer exists (*see, for example, Judgement of 12 February 2008 by the Constitutional Court in Case No. 2007-15-01, Para 4).* If the dispute no longer exists, the proceedings before the Constitutional Court become meaningless (*see Decision of 29 March 2010 by the Constitutional Court on Terminating Judicial Proceedings in Case No. 2010-68-01, Para 8).*

The fact that the norm that has been contested in a case has become invalid *per se* does not always serve as the grounds for terminating the case. I.e., in order to adopt a decision on terminating judicial proceedings, it is not always possible to apply only Para 2 of Section 29(1) of the Constitutional Court Law. The law envisages the possibility for the Constitutional Court to terminate judicial proceedings, but not an obligation to do so. The Constitutional Court must assess, whether no considerations exist pointing to the need of continuing the judicial proceedings (*see Judgement of 11 January 2011 by the Constitutional Court in Case No. 2010-40-03, Para 6*).

As regards cases, when the constitutionality of a norm that has become invalid is assessed until the moment of making the judgement, the Constitutional Court has noted that from the perspective of effectiveness of judicial proceedings, a judgement in such cases is meaningful only if it can have a retroactive force. Hence, judicial proceedings in such cases are possible, if the legal relationship under review allows granting a retroactive force to the judgement by the Constitutional Court (*see Judgement of 3 April 2008 by the Constitutional Court in Case No. 2007-23-01, Para 6*).

The assessment of the third sentence of Para 89 of Regulation 899, in the wording that is currently in force, in interconnection with the requirements included in Para 88 on ensuring sufficient reserves of medicinal products in pharmacies and the procedure of supply, allows concluding that patients are ensured the right to receive

both the cheapest reference medicinal products and the next cheapest medicinal products within the framework of the common name.

However, the Constitutional Court draws the attention of the Cabinet to the considerations presented by the Latvian Pharmacists Society that the wording of the third sentence in Para 89 of Regulation No. 899 requires aggregating information from all wholesalers of medicines and medicinal devices before dispensing the next cheapest reimbursement medicinal product to a patient. The pharmacies allegedly have no administrative resources at their disposal for complying with this requirement effectively. Thus, a possibility exists that in some cases accessibility of reimbursement medicinal products to patients within reasonable term could be delayed.

If the Constitutional Court were to declare the third sentence in Para 89 of Regulation No. 899 in the wording of 27 December 2011 invalid as of the moment of its adoption, it would not change the existing legal situation. The patients, to whom access to reimbursement medicinal devices was delayed because the contested norm prohibited dispensing other reimbursement medicinal products instead of the cheapest reference medicinal product, now have the right to receive the next cheapest reimbursement medicinal product in accordance with the wording of the third sentence in Para 89 of Regulation No. 899, which is currently in force. Thus, no circumstances exist pointing to the necessity to continue judicial proceedings in this part of the claim.

Thus, judicial proceedings regarding the compliance of the third sentence in Para 89 of Regulation No. 89, in the wording of 27 December 2011, with the Satversme must be terminated.

17. Finally, assessing, whether the State has fulfilled the obligations aimed at ensuring a person's fundamental rights, it must be verified, whether the general principles of law that follow from the Satversme have been respected. It follows from the application and other materials of the case that within the framework of this case the compliance of the contested norms with the principle of equality included in the first sentence of Article 91 of the Satversme must be assessed.

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

17.1. The main objective of the principle of equality, enshrined in the first sentence of Article 91 of the Satversme, is to ensure that such requirement of a judicial state as comprehensive impact of laws upon all persons and application of law without any privileges whatsoever were met. It also guarantees full impact of the law, unbiased and impassive application of it, and also that no one is allowed to disregard injunctions of law (*see Judgement of 14 September 2005 by the Constitutional Court in Case No. 2005-02-0106, Para 9.1).*

The Constitutional Court, in interpreting Article 91 of the Satversme, has recognised that the principle of equality prohibits state institutions to adopt such norms that without reasonable grounds allow differential treatment of persons, who are in similar and according to concrete criteria comparable circumstances. The principle of equality allows and even demands differential treatment of persons, who are in different circumstances, as well as allows differential treatment of persons, who are in similar circumstances, if there are objective and reasonable grounds for that (*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 29 December 2008 in Case No. 2008-37-03, Para 7*). Differential treatment has no objective and reasonable grounds, if it has no legitimate aim and if the relationship between the chosen means 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).*

17.2. In assessing the compliance of legal norms with the principle of equality, it must be first of all established, whether and which groups of persons are in similar and according to concrete criteria comparable circumstances.

The Applicant holds that those persons, who previously have received reimbursement medicinal products for a particular diagnosis, and the persons, who, within the framework of reimbursement procedure, have not previously received reimbursement medicinal products, are in similar and comparable circumstances. Both groups of persons allegedly have the right to receive similar medicinal products for dealing with health problems, thus they are in similar and comparable circumstances.

Whereas the Cabinet of Ministers does not uphold the Applicant's view and notes that the contested norms do not envisage differential treatment of comparable

groups of patients. The norms only differentiate the procedure, according to which a medical practitioner prescribes and the pharmacist dispenses medicinal products within the framework of reimbursement system, depending upon the stage of using medicinal products – first time use or continuous use. As regards patients, who have already previously received particular reimbursement medicinal products, the positive result of using the particular medicinal product has already been confirmed, and therefore it is useful to continue treatment with the same product. Such considerations are not applicable to those patients, who are receiving particular reimbursement medicinal products for the first time.

The Constitutional Court recognizes that the same disease, the treatment of which requires the same medicines or medicinal devices, is a feature, which unites all patients, irrespectively of the fact, whether they have previously received reimbursement medicines or medicinal devices envisaged for a particular diagnosis. However, a common feature *per se* cannot always serve as a sufficient argument for establishing that two groups of persons are in similar and comparable circumstances. The Constitutional Court must also assess, whether no significant considerations exist that indicate that these groups of persons are not in similar and comparable circumstances (*see, for example, Judgement of 15 March 2010 by the Constitutional Court in Case No. 2009-44-01, Para 14, and Judgement of 3 May 2012 in Case No. 2011-14-03, Para 13.2).*

In compliance with the procedure established by the contested norms, those patients, who within the framework of reimbursement procedure have already previously received particular reimbursement medicines or medicinal devices, retain this right in accordance with the procedure and in the scope established by Regulation No. 899. Whereas those patients, who become involved in the reimbursement system just now, have the right to receive the cheapest of the medicinal products of the common name.

The Cabinet of Ministers points to the special significance of the stage of medicines use and the patients' right to continue treatment with the medicines or medicinal devices they have received previously. In the course of using medicinal products patients may develop particular response to the impact of a particular medicinal product, as well as psychological certainty about the effectiveness of this

medicinal product. Also the representative of LAGP noted at the court sitting that ungrounded change of medicinal products can have an adverse impact upon the process of treatment. Neither does the Applicant contest such considerations.

It follows from the abovementioned, that medical considerations exist, due to which those patients, who have previously received particular reimbursement medicinal products or medicinal devices, must be ensured the possibility to continue the course of treatment that has been started. Whereas to those patients, who have not previously received particular reimbursement medicines or medicinal devices, the possibility to "continue" using them cannot be ensured at all, since they have never received the particular medicines or medicinal devices.

The Constitutional Court concludes that the groups of persons indicated by the Applicant are not in similar and comparable circumstances and the contested norms are not incompatible with the principle of equality enshrined in the first sentence of Article 91 of the Satversme.

Thus, the contested norms comply with Article 91 and Article 111 of the Satversme.

The Substantive Part

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

held:

1. To recognise Para 84^1 and the first and the second sentence of Para 89 of the 31 October 2006 Cabinet of Ministers Regulation No. 899 "Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment" compatible with Article 91 and Article 111 of the Satversme of the Republic of Latvia."

2. To terminate legal proceedings regarding compliance of the third sentence in Para 89 of the 31 October 2006 Cabinet of Ministers Regulation No. 899

“Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment par” with Article 91 and Article 11 of the Satversme of the Republic of Latvia.

The Judgement is final and not subject to appeal.

The Judgement enters into force as of the day of its pronouncement.

Chairperson of the court sitting G. Kūtris