

2007/01/16 - PL. ÚS 36/05: REIMBURSEMENT OF MEDICATIONS

HEADNOTES

According to Art. 1 para. 1 of the Constitution, the Czech Republic is a sovereign, unitary, and democratic state governed by the rule of law, founded on respect for the rights and freedoms of man and of citizens. All state authority emanates from the people; they exercise it through legislative, executive, and judicial bodies (Art. 2 para. 1 of the Constitution). The fundamental rights and basic freedoms shall enjoy the protection of judicial bodies (Art. 4 of the Constitution). According to Art. 36 para. 1 of the Charter of Fundamental Rights and Basic Freedoms, everyone may assert, through the legally prescribed procedure, his rights before an independent and impartial court or, in specified cases, before another body. The second paragraph of the same Article provides to everyone who claims that her rights have been curtailed by a decision of a public administrative authority the possibility, unless a law provides otherwise, to submit the matter to a court for review of the legality of that decision. However, judicial review of decisions affecting the fundamental rights and basic freedoms, the protection of which is enshrined in the constitutional order of the Czech Republic, may not be excluded from the jurisdiction of courts.

The decision on the inclusion of medicinal preparations into the list of medications covered by public health insurance funds results in an interference with the rights of their producers and distributors and, for that reason, it is necessary to see to it that the principles of fair process are consistently observed. Within the framework of abstract norm control, the Constitutional Court must adjudge whether the statutory framework creates conditions such that any interference would be balanced by such rights so as to eliminate, in a satisfactory manner, any room for arbitrariness in each concrete decision on the inclusion of medicinal agents into the list of medicines covered by public health insurance funds. Section 15 para. 10 of the Act on Public Health Insurance does not meet this requirement, as it does not guarantee the applicant that the decision on his application will be based on objective and verifiable criteria, be subject to judicial review, and be issued without unnecessary delay. The Ministry decides on the inclusion of a specific medication into the set of medicines fully covered by health insurance and into the set of medications only partially covered, as well as on the specific level of reimbursement, not in an administrative proceeding, but within the boundaries of the law-making process. It is therefore incompatible with the principle of the law-based state and, thus, in conflict with Art. 36 para. 1 of the Charter of Fundamental Rights and Basic Freedoms.

**CZECH REPUBLIC
CONSTITUTIONAL COURT
JUDGMENT**

IN THE NAME OF THE CZECH REPUBLIC

The Constitutional Court Plenum, composed of judges Stanislav Balík, František Duchoň, Vlasta Formánková, Vojen Güttler, Ivana Janů, Vladimír Kůrka, Dagmar Lastovecká, Jan Musil, Jiří Nykodým, Pavel Rychetský, Miloslav Výborný, Eliška Wagnerová and Michaela, Židlická, in the matter of the petition of a group of Senators of the Senate of the Czech Parliament, represented by advocate, JUDr. Ing. V. J., proposing the annulment of the provisions of § 15 para. 10 of Act No. 48/1997 Coll., on Public Health Insurance and on Amendments and Additions to certain Related Enactments, as subsequently amended, and the annulment of Regulation of the Ministry of Health No. 589/2004 Coll., on the Reimbursement of Medications and Foodstuffs for Special Medical Purposes, as amended, with the participation of 1) the Assembly of Deputies of the Parliament of the Czech Republic, 2) the Senate of the Parliament of the Czech Republic, and 3) the Ministry of Health of the Czech Republic, as parties to the proceedings, decided as follows:

Section 15 para. 10 and that portion of the final sentence of § 15 para. 5 of the Act on Public Health Insurance which follows the semicolon, reading, „the level of their reimbursement from health insurance shall be laid down in an implementing regulation,“ of Act No. 48/1997 Coll., on Public Health Insurance and on Amendments and Additions to certain Related Enactments, as subsequently amended, is annulled as of 31 December 2007. On the same day Regulation of the Ministry of Health No. 532/2005 Coll., on the Reimbursement of Medications and Foodstuffs for Special Medical Purposes, as subsequently amended, shall lose validity.

The proceeding on the petition proposing the annulment of Regulation of the Ministry of Health No. 589/2004 Coll., on the Reimbursement of Medications and Foodstuffs for Special Medical Purposes, as subsequently amended, is dismissed.

REASONING

I.

Definition of the Matter and Summary of the Petition

1. On 4 July 2005, the Constitutional Court received the petition of a group of 29 Senators of the Senate of the Czech Republic proposing the annulment of the provision of the Act on Public Health Insurance designated in the heading, as well as the ministerial regulation implementing it, due to their conflict with the Czech Republic's obligations resulting from Community law and from Article 36 para. 1 of the Charter of Fundamental Rights and Basic Freedoms (hereinafter „Charter“). The petitioners are of the view that, under the current legal scheme, authorized persons are not entitled to make a claim, in an administrative

proceeding, regarding the setting of the level of reimbursement from public health insurance for medicinal preparations and that they are denied the right to judicial and other protection against measures of the Ministry of Health of the Czech Republic (hereinafter „Ministry“) issued in this area.

2. The petitioners then described the manner in which the Czech Republic regulates by law the reimbursement of human medicines, as a component of the covered health care. It is contained in Act No. 48/1997 Coll., on Public Health Insurance and on Amendments and Additions to certain Related Enactments, as subsequently amended (hereinafter „Act on Public Health Insurance“).

3. As part of the provision of health care, certain medicinal preparations and foodstuffs for special medical purposes (hereinafter „medications“) are covered from health insurance funds. They are the medications which contain substances from groups of medicinal substances listed in the Annex (Annex No. 2) to the Act on Public Health Insurance. Each group of medicinal substances listed in the Annex must contain at least one medicinal preparation or foodstuff for special medical purposes which is fully covered by health insurance. As a prerequisite for health insurance to reimburse medications, they must be entered into the list of medicinal preparations and foodstuffs for special medical purposes which is kept by the Ministry. The request to enter them into the list is submitted by the holder of a decision, issued by the State Institute for the Supervision of Medications, on the registration of a medication in accordance with Act No. 79/1997 Coll., on Medications and on Amendments and Additions to certain Related Enactments. The decision not to enter into the list a particular medicinal preparation or foodstuff for special medical purposes, as well as the decision to remove it from the list, is made by the Ministry in an administrative proceeding.

4. If the State Authority for the Supervision of Medications has decided to register a medication, the Ministry of Finance of the Czech Republic sets, in conformity with Act No. 526/1990 Coll., on Prices, as subsequently amended, its maximum price, and the holder of the registration decision may request the Ministry to enter the medication into the list and can submit to the Ministry a proposal to set the level of reimbursement for the medication from public health insurance funds. Without the Ministry having any obligation to follow such proposals, the Ministry issues a regulation in which it enumerates the medications which are fully reimbursed from health insurance, as well as the level of reimbursement for individual medicinal substances. Proposals to set the level of reimbursement are submitted to the Ministry, which then refers them to the Classification Commission, an advisory body of the Ministry of Health. The Classification Commission discusses individual proposals and recommends the level of reimbursement; the Commission's recommendations are then published on the Ministry's web site. The appropriate division of the Ministry subsequently draws up a proposed regulation and, together with comments on the recommended level of reimbursement, refers it once again to the Classification Commission. Before work on the draft implementing regulation is completed, those submitting proposals are one again afforded the opportunity to give their views on the classification process, albeit to a significantly restricted scope. The resulting draft legal enactment is then sent to the Ministry of Health, which, after the completion of the comment proceeding, submits it to the Government Legislative Council. If the Council adopts a positive

position on the legal enactment, it is then promulgated.

5. A listing of fully covered medications is then drawn up, and the amount of reimbursement of medicinal substances is set in a legislative process. Participation in this process by the holders of a registration for a medication and other interested persons, thus also their opportunity to affect the form of the regulation, depends solely on the will of the Ministry to inform them that it is under preparation and to heed their proposal and observations on it. It works similarly for the initiative to revise the content of the regulation. In addition, the empowering provision of the Act on Public Health Insurance does not contain any more detailed criteria for setting the level of reimbursement of medications, and the resulting content of the regulation is not based on objective and verifiable criteria. As it is a legal enactment, the regulation also does not contain any substantiation.

6. The setting of the level of reimbursement of medications from health insurance funds does not occur in the context of individual administrative proceedings with the participations of proposers-registration holders endowed with procedural rights. Persons are not entitled to claim rights relating to the level of reimbursement before an independent and impartial court.

7. Decisions on the reimbursement of medications in the Czech Republic are thus not founded on objective criteria, are not substantiated, and are not subject to judicial review. These defects are not cured even by the fact that the medications are integrated into the system of health insurance in a proceeding on the inclusion of medications into the list of medicinal preparations and foodstuffs for special medical purposes, which is in essence an administrative proceeding. While the inclusion of a medication into the list is a pre-condition of their inclusion into the system of repayment, still it does not have even the least influence on the level of reimbursement for specific medications.

8. The petitioners draw attention to the fact that the setting of prices for human medications and their integration into the system of public health insurance is regulated for the Member States of the European Union, by Council Directive No 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (hereinafter "the Directive"). Article 1 of the Directive imposes upon Member States the obligation to ensure that all legal or administrative measures to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of the Directive. According to Article 6 para. 2 of the Directive, a decision not to include a medicinal product in the list must contain a statement of reasons based upon objective and verifiable criteria, including, where necessary, any expert opinions or recommendations on which the decision is based. In such cases, the applicant should be informed of remedies available to her. In the petitioners' view Article 6 must be interpreted in conjunction with Article 1. The mere inclusion of a medication into the system of public health insurance by means of a list has no practical effect, to the extent that a decision is not made at the same time on the level of reimbursement for the medication from public health insurance. The principles of Article 6 must be

applied not only to decisions to include a medication into the list, but also to Ministry's decisions on the actual level of reimbursement from health insurance.

9. The petitioners are of the view that the Czech Republic's accession to the European Union on 1 May 2004 resulted in the inclusion of Community law into the Czech legal order. This has direct impact also on the perception of the concept of the constitutional order. The norms of primary law of the European Community now also constitute a component thereof. The principle of applicational precedence follows therefrom, as does the duty duly to implement into the national legal order obligations arising from European law. The petitioners regard the Constitutional Court as the body which oversees the respect for these principles, so that it is empowered to review the conformity of relevant domestic legal norms with the norms of Community law; in this regard, then, it is endowed with the competence to derogate domestic norms. According to the petitioners, the respect for, and supervision of, the observance of the duty duly to implement domestically the obligations under European law represents the effectuation of the attributes of a law-based state in accordance with Art. 1 para. 1 of the Constitution of the Czech Republic, and this obligation extends to the plane of the constitutional order.

10. Subsidiarily, the petitioners then add, without more detailed constitutional arguments, that, if holders of a decision to register medications are denied the right to claim their right „before an independent and impartial administrative body or court“, then the contested legal scheme in relation thereto violates the right to judicial and other protection under Article 36 para. 1 of the Charter.

II. A)

Summary of the Significant Portions of the Statements of Views of Parties to the Proceeding

11. In conformity with § 69 of Act No. 182/1993 Coll., on the Constitutional Court, as subsequently amended (hereinafter „the Act on the Constitutional Court“), the Constitutional Court sent the petition initiating the proceeding to the parties to the proceeding - the Assembly of Deputies and the Senate of the Parliament of the Czech Republic, the Ministry of Health of the Czech Republic, and the Public Defender of Rights.

12. As regards the content of the petition, the Assembly of Deputies stated that the petition is premised on the legal situation existing prior to the adoption of two amendments to the Act on Public Health Insurance, introduced by Act No. 438/2004 Coll. (which amends Act No. 551/1991 Coll., on the General Health Insurance Company of the Czech Republic, as subsequently amended, Act No. 280/1992 Coll., on Departmental, Trade Union, Enterprise and other Health Insurance Companies, as subsequently amended, Act No. 592/1992 Coll., on Insurance Premiums for the General Health Insurance Company, as subsequently amended, and Act No. 48/1997 Coll., on Public Health Insurance and on Amendments and Additions to certain Related Enactments, as subsequently amended), which entered into force on 1 August 2004, and Act No. 123/2005 Coll. (which amends Act No. 48/1997 Coll., on Public Health Insurance and on Amendments and Additions to certain Related

Enactments, as subsequently amended, and Act No. 592/1992 Coll., on Insurance Premiums for the General Health Insurance Company, as subsequently amended), which entered into force on 30 March 2005. The first of the mentioned acts incorporated the substance of Council Directive No. 89/105/EEC into the Act on Public Health Insurance in the sense that § 15 para. 8 of that Act now allows for the review, in accordance with the Administrative Code, of a decision to remove a medication from the list of medicinal preparations or foodstuffs for special medical purposes, and the holder of a decision to register a medication is also ensured legal protection before „an independent administrative body“. The second of the mentioned acts introduced the same manner of proceeding into § 15 para. 6 of the Act on Public Health Insurance for decisions not to include a medication into the list of medicinal preparations or foodstuffs for special medical purposes. The Assembly of Deputies is thus of the view that the contested provision is no longer in conflict with the mentioned Directive. The Assembly of Deputies did not, however, express any view on the objection that the legal scheme conflicts with the principle of the right to judicial protection.

13. First of all the Senate observed that, on 20 May 2004, it debated the bill to amend the Act on Public Health Insurance (subsequently promulgated as No. 438/2004 Coll.), which introduced the contested provision, and decided at that time to return it to the Assembly of Deputies with proposed amendments. No objections were raised to the currently contested provision, and the Senate considered it as corresponding to the right of citizens to be provided health care, in the sense of Art. 31 of the Charter. In the version approved by the Senate, the bill was then adopted by the Assembly of Deputies. The Senate then draws attention to the fact that the petitioners are themselves, as they assert, aware of the fact that the petition is of a non-standard character, to the extent that a statutory provision is contested primarily due to its conflict with Community law. According to the Senate, however, the ascertainment of whether domestic law is in conformity with Community law cannot be within the competence of a domestic body. It is solely the European Court of Justice which is competent in this respect. The principle of applicational precedence of Community law speaks in favor of this conclusion, as does the institute of the preliminary questions, in which national courts refer matters to the European Court of Justice; if the Constitutional Court could annul statutes or individual provisions thereof due to their conflict with Community Law, it would also be authorized to respond to preliminary questions. Naturally that is not the case. The protection of rights arising from Community law is ensured by other means, primarily by the responsibility of Member States for the violation thereof. The Senate leaves it to the Constitutional Court to make the assessment of the asserted conflict between the contested provision of the Act on Public Health Insurance and Article 36 para. 1 of the Charter.

14. In reaction to a specific query by the Justice Rapporteur, the then Minister Milada Emmerová on behalf of the Ministry of Health, gave its views on the process of adopting the contested regulation. She asserted that the norm-making process corresponded to the general manner of adopting regulations. In conformity with the Legislative Rules of the Government, the proposed regulation was received by all bodies required to give comments. After the comments were incorporated into it, it was discussed by the Government Legislative Council, which certified its

conformity with the constitutional order and statutes. The regulation was signed by the Minister and was subsequently promulgated in the Collection of Laws. As far as concerns the process of preparing the regulation's substantive content, it was governed by the Ministry's internal regulations, namely Minister's Order No. 3/1992, for Ensuring Legislative Activity at the Ministry of Health of the Czech Republic, Order No. 12/2003, on the Principles for the Distribution of Materials of the Ministry of Health of the Czech Republic for Internal and External Comment Proceedings, and Order No. 6/2004, on the Statute and Rules of Procedure of the Commission of the Ministry of Health of the Czech Republic for the Classification of Medications and Foodstuffs for Special Medical Purposes. The transparency, representativeness, and impartiality of the setting of the level of reimbursement is ensured by the composition of the Classification Commission, whose members are appointed and removed by the Minister. The Ministry gives as examples the representatives of the Czech Jan Evangelista Purkyně Medical Society, the Czech Medical Chamber, the Czech Pharmaceutical Chamber, the Czech Dental Chamber, organizations of patients and health insurance companies, and the State Institute for the Supervision of Medications. In its work, the Classification Commission observes the prescribed rules and abides by the principle of transparency when drafting and evaluating proposals and complaints of proposers, and the principle of objectivity and quality of provided evaluations of proposals and analyses of objections.

15. The Ministry rejects the petitioners' arguments regarding the transposition of the Directive into the Act on Public Health Insurance. In the Ministry's view, the Directive distinguishes, on the one hand, the decision on the inclusion of medications into the list of medicinal preparations or foodstuffs for special medical purposes and, on the other, the setting of the price of a specific medication. If the Directive speaks of „decisions on price“, then it is merely reacting to the various systems found in the Member States for the setting of prices, without thereby imposing an obligation to set the price of medications through an administrative proceeding. Thus the petitioners have joined, without justification, two separate processes, that is, the decision on the inclusion into the list of medications covered by health insurance funds and the approval of the price of this medication. The Directive neither regulates the setting of the price of medications nor requires that decisions on it be in the context of an administrative proceeding. The obligations from the Directive have thus been properly and fully implemented.

16. The Ministry considers as a mere general assertion the petitioners' objection relating to the violation of the rights, arising from Art. 36 para. 1 of the Charter, of the holders of a decision to register a medication. It is of the view that the precondition for this objection to be successful would be a „violation of a specific right prescribed by a legal enactment“, and that the petitioner „would have to specifically designate which legal enactment laid down the right they cite and in what specifically the violation thereof consists“. The Ministry further observes that a medication can be introduced onto the market without regard to whether it is at least partially covered from public health insurance funds and that manufacturers and distributors need not undergo the process of setting the reimbursement. It considers the petition as manifestly unfounded and, as such, proposes it be rejected on preliminary grounds.

17. The Public Defender of Rights informed the Justice Rapporteur, in his 29 July 2005 letter, that he would not intervene into the proceedings to review the petition.

II. B)

The Positions of Further Affected Subjects and Experts

18. In the endeavor to obtain the most complete information possible concerning the process of creating the catalogue of medications reimbursed from public health insurance funds, the Constitutional Court also requested other interested institutions to inform it of their positions on the petition of the group of Senators before the Court. In addition, the Czech Medical Chamber spoke to this matter, as did the Czech Pharmaceutical Chamber, the General Health Insurance Company of the Czech Republic, and the Federation of Health Insurance Companies, in which are affiliated all other insurance companies operating in the Czech Republic in the area of public health insurance, specifically the Czech National Health Insurance Company, the Metallurgical Employee Insurance Company, the Departmental Health Insurance Bank, Insurance Company and Building Company, the Mining Fraternal Treasury, the Military Health Insurance Company, the Employee Insurance Company - Škoda, the Health Insurance Company - METAL-ALIANCE, and the Health Insurance Company of the Czech Ministry of Interior.

19. In its statement of position, the Czech Medical Chamber fully supported the petition and also agreed with the grounds which led the petitioner to submit it. It considers it as undesirable for the setting of the prices of medications, as defined in the contested statutory provision, to take place in a system into which persons who should take part in that task do not have the opportunity to intervene; it named as examples doctors' professional organizations, representatives of health insurance companies, scientific institutions and manufacturers of medications. It acknowledged that although its representatives number among the members of the Commission for the Classification of Medications, however, that Commission has not been convened for the last six months, so that the Commission was not consulted at all with regard to the most recent amendment to the contested regulation. The Czech Medical Chamber confirms that regulations are adopted in a thoroughly informal manner, without an objective assessment of all viewpoints; for example, its comments on the draft of the most recent amendment of this regulation was not in any respect taken into consideration. Under the existing situation, the rights of producers of medications, as well as of patients themselves, can be harmed. The General Health Insurance Company of the Czech Republic also agrees with the grounds which led the group of Senators to submit this petition. The empowering provision of the Act on Public Health Insurance does not contain more detailed criteria for setting the level of reimbursement of individual medications. In consequence the Ministry is afforded extensive opportunity to decide in a subjective fashion, both as regards the medications that will be fully covered by the system of public health insurance and the level of partial reimbursement. In contrast, other interested persons are de facto excluded from this process, which they cannot actively influence. In addition, these persons cannot seek the protection of their rights before an independent and impartial court. The existing legal arrangement for setting the prices of medications does

not correspond to the requirements of the Directive, which the Czech Republic has not properly implemented. The Czech Pharmaceutical Chamber stated that it has repeatedly in the past criticized the current form of the process of classification (that is, the inclusion of medications among those which are covered by public health insurance funds), citing a whole host of non-transparent steps, which in its view seriously threatens the effective functioning of the whole system of the reimbursement of medications. It is, on the one hand, a fact that the level of reimbursement of medications is set, taking into account their maximum administrative price, as of a specific date when it will still be a long time before stocks of the medication on the market will be sold out. In practice however, quite commonly the situation arises where insurance companies refuse to reimburse that part of the price of medications, declared to be covered in full, exceeding the newly set maximum price. The Czech Pharmaceutical Chamber further considers as non-transparent the role of the Classification Commission in the process of drafting the regulation. It has the status of a mere advisory body, and it has occurred in the past that, after interventions by the Ministry, the resulting form of the regulation diverged from the form of the draft discussed by the Classification Commission. Affected persons may submit comments on the results of its action only during a very short time interval, which allows no opportunity for consideration of the most fundamental possibilities of repercussions of the proposed changes. In the past, the time elapsing between the drafting, issuance and coming into force of a relevant amendment has been much shorter than required for the health care field to be prepared or for expert discussion. It is only in the period of time between the completion of drafting the regulation and its coming into force that the General Health Insurance Company of the Czech Republic prepares the „Number Book“, and not before they have access to this aid does the public, and even health care professionals, comprehend how this or that specific medication will be reimbursed. This Number Book is often issued only at the moment a new regulation comes into effect, if not later. Imprecise information on the level of surcharges then burdens patients and results in financial harm to pharmacies. The Czech Pharmaceutical Chamber would welcome it if a clear and binding deadline were set for the drafting, issuance, and entry into force of the reimbursement regulation, which would guarantee sufficient extra time for doctors, pharmacists, and patients to prepare themselves for the new system of reimbursement. The Federation of Health Insurance Companies did not inform the Constitutional Court of its position on the petition under consideration.

20. In view of the discussion currently being held in the expert literature on the question of the constitutionality of Czech Republic legal enactments which are considered to be in conflict with Community law, in which divergent positions have been taken, the Justice Rapporteur requested from the centers of scholarship, that is the relevant departments of individual law faculties in the Czech Republic to give their expert views on this issue.

21. The views expressed in their responses fall into three basic groups. The first proceeds strictly from the conclusion that, since it does not form a part of the constitutional order, Community law cannot be a referential criteria for the adjudication of the constitutionality of domestic statutes. The second takes the position that the adjudication of whether statutes of the Czech Republic are in conformity with primary and secondary law of the European Community cannot be

ruled out, namely, where apart from their conflict with Community law, they also come into conflict with the principles of the Czech Republic's constitutional order. The third group distinguishes the case of proper transposition of Community law into the Czech legal order, which unequivocally eludes review of its constitutionality from the case of defective transposition, which is subject to the abstract review of constitutionality, as in such a case the legislature has not acted within the confines of its delegated competence. It can be deduced therefrom that, even if the Constitutional Court cannot, within the context of abstract norm control, annul a legal enactment due to its conflict with Community law, in order for it to be possible to assess in specific cases its competence to annul such an enactment, it must always reach a conclusion on the enactment's conformity or conflict with this law. The Constitutional Court reveals in advance that it has itself, below in the reasoning, taken a position on the possibilities of reviewing implemented Community law.

III.

The Wording of the Contested Provisions

A)

22. Sec. 15 para. 10 of Act No. 48/1997 Coll., on Public Health Insurance and on Amendments and Additions to certain Related Enactments, as subsequently amended, reads as follows:

„The Ministry of Health shall lay down in a regulation

- a) the medicinal preparations and foodstuffs for special medical purposes which are compensated in full by health insurance;
- b) the level of compensation of individual medicinal substances belonging to the group of medicinal substances according to Appendix No. 2;
- c) the level of compensation for foodstuffs for special medical purposes containing medicinal substances from the group of medicinal substances according to Appendix No. 2;
- d) the level of compensation from health insurance of individually prepared medicinal preparations, radiopharmaceuticals and transfusion preparations;
- e) restrictions and symbols fixing the conditions prescribed for medicinal preparation and foodstuffs for special medical purposes reimbursed from health insurance, including restrictions and symbols for the use of medicinal preparation and foodstuffs for special medical purposes for the provision of health care at specialized facilities.“

23. Sec. 15 para. 5, the last sentence after the semi-colon, of Act No. 48/1997 Coll., on Public Health Insurance and on Amendments and Additions to certain Related Enactments, as subsequently amended, reads as follows:
„The level of their reimbursement from health insurance shall be laid down in an implementing regulation.“

B)

24. Regulation of the Ministry of Health No. 532/2005 Coll., on the Reimbursement of Medications and Foodstuffs for Special Medical Purposes, as amended by Regulation of the Ministry of Health No. 37/2006 Coll., Regulation of the Ministry of Health No. 368/2006 Coll., Regulation of the Ministry of Health No. 387/2006 Coll.,

and Regulation of the Ministry of Health No. 621/2006 Coll., reads as follows:
„The Ministry of Health shall lay down pursuant to § 15 para. 10 Act No. 48/1997 Coll., on Public Health Insurance and on Amendments and Additions to certain Related Enactments, as amended by Act No. 438/2004 Coll., (hereinafter the ‘Act’):

§ 1

This Regulation lays down:

a) the medicinal preparations and foodstuffs for special medical purposes which are reimbursed in full from public health insurance funds (hereinafter „health insurance“), which are listed in Appendix No. 1 to this Regulation;

b) the level of reimbursement for individual medicinal substances belonging to the groups of medicinal substances under Appendix No. 2 to the Act, which are listed in Appendix No. 1 to this Regulation;

c) the level of reimbursement for foodstuffs for special medical purposes, containing medicinal substances from the group of medicinal substances under Appendix No. 2 to the Act, which are listed in Appendix No. 1 to this Regulation;

d) the level of reimbursement from health insurance of individually prepared medicinal preparations, radiopharmaceuticals and transfusion preparations which are listed in Appendix No. 1 to this Regulation;

e) restrictions and symbols fixing the conditions prescribed for medicinal preparation and foodstuffs for special medical purposes reimbursed from health insurance, including restrictions and symbols for the use of medicinal preparation and foodstuffs for special medical purposes for the provision of health care at specialized facilities, which are listed in Appendix No. 2 to this Regulation.

§ 2

The following are repealed:

Regulation No. 589/2004 Coll., on the Reimbursement of Medications and Foodstuffs for Special Medical Purposes.

Regulation No. 225/2005 Coll., which amends Regulation No. 589/2004 Coll., on the Reimbursement of Medications and Foodstuffs for Special Medical Purposes.

Regulation No. 337/2005 Coll., which amends Regulation No. 589/2004 Coll., on the Reimbursement of Medications and Foodstuffs for Special Medical Purposes.

§ 3

This Regulation shall come into effect on 1 January 2006.

Minister: MUDr. Rath (signature).“

IV.

Conditions for Petitioners‘ Standing

25. The petition proposing the annulment of § 15 para. 10 of the Act on Public Health Insurance and on Amendments and Additions to certain Related Enactments, as subsequently amended, and the annulment of Regulation of the Ministry of Health, No. 589/2004 Coll., on the Reimbursement of Medications and Foodstuffs for Special Medical Purposes, as subsequently amended, was submitted by a group of twenty-nine Senators of the Senate of the Czech Parliament, thus in conformity with the conditions contained in § 64 para. 2, lit. b) of Act No. 182/1993 Coll., on the Constitutional Court, as subsequently amended. In the current matter, it can

be affirmed that the petitioners have satisfied the standing conditions.

V.

The Constitutional Conformity of the Legislative Process

26. In conformity with § 68 para. 1 of the Act, in proceedings on the review of statutes or other legal enactment, the Constitutional Court is obliged to assess whether the contested legal enactment was adopted and issued in the constitutionally-prescribed manner.

27. It was ascertained from the relevant internet sites that the bill to amend the Act on Public Health Insurance was submitted to the Assembly of Deputies by the Government of the Czech Republic on 8 September 2003. By its resolution No. 1035 of 6 April 2004, the lower chamber approved the bill by a majority of 87 Deputies from the 170 present, while 79 Deputies voted against the bill.

28. The Senate debated the transmitted bill on 20 May 2004, and by its resolution No. 450, with a majority of 56 of the 57 present Senators, pronounced its decision to return the bill, with proposed amendments, to the Assembly of Deputies.

29. The Assembly of Deputies debated the returned bill on 24 June 2004 and, by its resolution No. 1199, expressed its approval of the bill in the wording adopted by the Senate. Of the 189 Deputies present, 119 voted in favor and 36 against the bill.

30. The President of the Republic signed the law on 14 July 2004, as did the Prime Minister on 16 July 2004.

31. On 26 July 2004 the Act was promulgated in the Collection of Laws, Part 144, No. 438/2004 Coll.

32. The authority of the Ministry to issue legal enactments for the implementation of statutes is based on Art. 79 para. 3 of the Constitution of the Czech Republic. The prerequisite therefor is the existence of an explicit statutory empowerment. In the given case, this empowerment was given precisely in § 15 para. 10 of the Act on Public Health Insurance. The regulation indicated in the petition was signed by the Minister of Health and duly promulgated in Part 202 of the Collection of Laws, as No. 589/2004. The regulation currently in force was also signed by the Minister of Health and was duly promulgated in Part 181 of the Collection of Laws, as No. 532/2005.

33. The Constitutional Court has thus established that the adoption and issuance of the legal enactment, which are the subject of review, were adopted and issued in the prescribed manner.

VI. Actual Review

34. The petitioners contest the empowering provisions of the Act on Public Health Insurance on two independent grounds. In their view it conflicts, on the one hand, with the fundamental attributes of the law-based state, that is, the State's obligation to respect Community Law (Art. 6 of the Transparency Directive), with which it conflicts, and, on the other hand, it neglects the guarantee of judicial protection, as it is enshrined in Art. 36 of the Charter.

35. In its Judgment No Pl. US 50/04 (No. 154/2006 of the Collection of Laws), the Constitutional Court explained that Community law could not serve as a referential criterion for its adjudication of the constitutionality of domestic enactments. On the other hand, the European Communities, just the same as is the Czech Republic, are law-based communities. The European Communities are constructed on the respect and esteem for the essential attributes of a law-based state. As can be deduced from the jurisprudence of the European Court of Justice, its interpretation of general legal principles corresponding to the fundamental rights contained in national constitutional catalogues, is quite similar to the Constitutional Court's approach. Moreover, the issue under adjudication concerns the establishment and functioning of the internal market including interferences with the free movement of goods, one of the four fundamental freedoms, or the very foundations of the European Communities; it is therefore necessary to pay careful attention as to whether the adopted restrictions are balanced by a sufficient guarantee of the participating subjects' fundamental rights, in the case under adjudication, above all the right to due process and fair proceedings. The Constitutional Court also dealt, in this spirit, with the petitioners' objection that the contested provision of the Act on Public Health Insurance is in conflict with the directive. Even were such conflict actually to be ascertained, that could not, in and of itself, result in the derogation either of the statutory provision at issue or of the regulations implementing it; nonetheless, the arguments justifying one in ascertaining conflict with the directive could support the substantiation of unconstitutionality.

36. According to Art. 1 para. 1 of the Constitution, the Czech Republic is a sovereign, unitary, and democratic state governed by the rule of law, founded on respect for the rights and freedoms of man and of citizens. All state authority emanates from the people; they exercise it through legislative, executive, and judicial bodies. (Art. 2 para. 1 of the Constitution). The fundamental rights and basic freedoms shall enjoy the protection of judicial bodies (Art. 4 of the Constitution). According to Art. 36 para. 1 of the Charter, everyone may assert, through the legally prescribed procedure, his rights before an independent and impartial court or, in specified cases, before another body. The second paragraph of the same Article provides to everyone who claims that her rights have been curtailed by a decision of a public administrative authority the possibility, unless a law provides otherwise, to submit the matter to a court for review of the legality of that decision. However, judicial review of decisions affecting the fundamental rights and basic freedoms, the protection of which is enshrined in the constitutional order of the Czech Republic, may not be excluded from the

jurisdiction of courts.

37. In the Czech legal order, the system for the regulation of the market in medical preparations is divided into four distinct steps: the registration of a medication (approval of its introduction onto market), the setting of its maximum price, the decision on its inclusion on the list of reimbursable medications, and the setting of the level of reimbursement from public health insurance funds. The State Institute for the Supervision of Medications makes the decision on the registration of a medication pursuant to § 26 of Act No. 79/1997 Coll., on Medications and on Amendments and Additions to certain Related Enactments; the Administrative Procedure Code (see § 66 of the mentioned Act) applies to such decisions. The Ministry of Finance sets the maximum price in conformity with § 10 of Act No. 526/1990 Coll., on Prices, as subsequently amended, and it publishes, in the Bulletin of Prices, an official notice containing a list of goods with regulated prices. The significance of the third step consists in the fact that a medication can only be reimbursed from public health insurance funds if it is entered into the list, kept by the Ministry, of medicinal preparations or foodstuffs for special medical purposes. If the Ministry does not grant the application of a producer or distributor of a medication to enter a certain medication into this list, the Administrative Procedure Code applies to such decision. The Administrative Procedure Code also applies to decisions to remove medications from the list. The first and third steps then are conducted in accordance with the rules of the Administrative Procedure Code, where the issuance of an individual decision is preceded by a proceeding ensuring to the parties the possibility to assert their procedural rights; in view of the subject of the proceeding, the particular regime for the regulation of the prices of medications are left aside. In contrast thereto, the last step no longer provides for a decision in the form of an individual administrative act. It is in the form of a ministerial regulation, but in its essence it is not a general norm, rather „a bundle of individual decisions“; therefore, it would be appropriate to apply to it the regime foreseen in Art. 36 para. 1 or alternatively para. 2 of the Charter.

38. At the same time, the setting of a specific level of reimbursement holds basic significance for the demand of any given medication, namely according to the principle, the higher the share of reimbursement from public health insurance, the higher is the demand. The Ministry's decision on the concrete level of reimbursement of any given medication, alternatively, as in our case, its decision regarding in what form it prepares and promulgates the regulation at issue, is then reflected in the economic performance and the success of the respective producer or distributor. In its own way, the creation of unequal conditions for engaging in business deforms the free competition on the market in medications for human use. The conditions for engaging in business must naturally be the same for all participants, even as far as concerns the limitation thereof by the given Act. All producers and distributors of medicinal preparations can engage in business on the domestic market only if they satisfy the prescribed statutory conditions, which, however, must be the same for all. To the extent that, as a result of the inclusion of certain preparations into the list of medications covered from public health insurance funds, their producers or distributors gain an advantage, all the more thoroughly must care be taken that this inequality is balanced by the opportunity to scrutinize the transparency of the creation of these conditions, moreover, in

each case individually.

39. This is otherwise also the objective of the Directive recalled by the petitioners. Article 6 thereof states that it applies “. . . if a medicinal product is covered by the national health insurance system only after the competent authorities have decided to include the medicinal product concerned in a positive list”. The terms of the Article require that all such decisions be taken in the form of an individualized administrative decision (in other words, that the applicant be given a statement of reasons based upon objective and verifiable criteria), that decisions be given within 90 or 180 days, and that decisions be subject to judicial review (stated in a comprehensive manner, it formulates a certain set of procedural rights for the protection of parties). As is clear from its wording, § 15 para. 10 of the Act on Public Health Insurance does not require these guarantees.

40. For the reasons analyzed in greater detail in the already cited judgment, Judgment No. Pl. US 50/04, the Constitutional Court construes Art. 36 para. 1 and para. 2 of the Charter while taking into account the jurisprudence of the European Court of Justice relating to the principle of fair process. The European Court of Justice has already twice resolved analogous issues, specifically in relation to the Austrian and Finnish systems for the reimbursement of human medications. As appears from the case, *Commission v. Finland*, (Case C-229/00, *Commission v. Finland*, [2003] ECR I-5727), Finland had a system for the reimbursement of medicinal preparations from public health insurance similar to that of the Czech Republic. According to Finnish law, as a result of the decision on pricing, medicines were automatically entered onto the list of reimbursable medicines, which meant that a claim arose to the reimbursement from public insurance of 50 % of their price. Finnish law thus called for a bifurcated decision-making process only in cases concerning those medicines which were reimbursed from the public health insurance system at a rate higher than 50 %. For that purpose the Council of Ministers formulated, by decree, a list of “certain active ingredients” which enjoy higher rates of reimbursement. The actual decision about higher reimbursement for specific medicines was issued by experts in individual cases, but such decision were simply a pro forma confirmation that particular medicines contained an active ingredient included in the Council of Minister’s list. With reference to the mentioned structure of decision-making, the Finnish government argued that Art. 6 of the Directive did not apply to the enactment issued by the government because, in and of itself, it “does not result in a medicinal product being entered on the list of medicinal products qualifying for higher-rate cover, but refers to certain active ingredients” (Id., para. 30) The European Court of Justice rejected this rather formalistic contention as it found that the Council of Ministers’ decree (even though indirectly) predetermines certain medications to qualify for a higher-rate of reimbursement and that, although in the form of a general legal act, in fact “the Council of Ministers’ decision constitutes a bundle of individual decisions on the inclusion of certain medicinal products in one of the social security schemes, so as to bring it within the provisions of Article 6 of the directive.” (Id., para. 34).

The case of the *Commission v. Austria* (Case C-424/99, *Commission v. Austria*, [2001] ECR I-9285) presented a similar problem. In the Austrian system there was a register of medicinal preparations for the purposes of their reimbursement, but it represented merely a “working tool”, and the decision on the reimbursement of

particular medicines from the system of health insurance scheme was made in individual instances. In individual cases doctors could decide, on the basis of the patient's need, that medicines included on the register would not be reimbursed and those not on the register would be. Accordingly, the Austrian government maintained that its register did not qualify as a precise list in the sense of Art. 6 of the Directive. The European Court of Justice stated that the purpose of the Directive is to ensure that any "measure to control the prices of medicinal products . . . or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of the directive" (para. 30). Therefore, in order to bring the system within the application of Art. 6 of the Directive, the European Court of Justice concluded that, regardless of the merely guidance function of the register, it was sufficient that "inclusion of a medicinal product on the register normally means that its cost will automatically be borne by the scheme". Therefore, the European Court of Justice has twice clearly held that decisions concerning the level of reimbursement of cost of medicines by the national health insurance system, even if formally separated from decisions on inclusion in a list, are covered by Art. 6, so that they must be accompanied by the procedural safeguards contained therein.

41. As was already explained above, the way in which the European Court of Justice construes the principles corresponding to the fundamental rights and freedoms necessarily has repercussions when domestic law and its conformity with constitutionally protected rights are construed. Art. 1 of the Charter bestows special protection upon fundamental rights. If then that Court concluded that the decision on the inclusion of medicinal preparations into the list of medications covered by public health insurance funds results in an interference with the rights of their producers and distributors and, for that reason, it is necessary to see to it that the principles of fair process are consistently observed, then the Constitutional Court must take this line of argument into account when interpreting Art. 36 para. 1 or para. 2 of the Charter. Within the framework of abstract norm control, it is necessary to adjudge whether the statutory framework creates conditions such that any interference would be balanced by such rights so as to eliminate, in a satisfactory manner, any room for arbitrariness in each concrete decision on the inclusion of medicinal agents into the list of medicines covered by public health insurance funds. Section 15 para. 10 of the Act on Public Health Insurance does not meet this requirement, as it does not guarantee the applicant that the decision on his application will be based on objective and verifiable criteria, be subject to judicial review, and be issued without unnecessary delay. The Ministry decides on the inclusion of a specific medication into the set of medicines fully covered by health insurance and into the set of medications only partially covered, as well as on the specific level of reimbursement, not in an administrative proceeding, but within the boundaries of the law-making process.

42. On the strength of the empowerment contained in the provisions of the Act on Public Health Insurance, the Ministry regulates by means of a regulation, that is, a generally binding legal enactment, the rights and obligations of precisely individually defined persons, which is typically accomplished through the application of law. The existing practice thereby departs from one of the foundational substantive characteristics of the concept of a statute (legal

enactment), which is its general character.

43. The Constitutional Court has already in the past repeatedly given its views on the requirements that legal enactments be of a general character. In this context, it stated in its Judgment No. Pl. US 55/2000, The Collection of Judgments and Rulings of the Constitutional Court, Vol. 22, p. 55 and foll.: „Among the foundational principles of the material law-based state belongs the maxim that legal rules be of a general character (the requirement of the generality of statutes, alternatively of the generality of legal enactments). The general character of the content is an ideal, typical, and essential characteristic of a statute (alternatively, of legal enactments in general), as distinct from court judgments and governmental and administrative acts. The purpose of the division of state power into legislative, executive and judicial powers is to entrust the state’s general and primary power of regulation to legislation, its derived general power of regulation, as well as decision-making in individual cases, to administration, and exclusively decision-making of individual cases to the judiciary. From the stated demarcation of the definitional characteristics of the concept of a statute (alternatively, of a legal enactment), is then deduced the concept of the statute (legal enactment) in the substantive sense, from which must be distinguished statutes (legal enactments) in the formal sense.“ The Constitutional Court has subsequently affirmed this conclusion, for ex., in its 28 June 2005 Judgment No. Pl. US 24/04.

44. In the matter of the proceedings on the petition proposing the annulment of § 7 of Act No. 2/1991 Coll., on Collective Bargaining, the Constitutional Court also decided on the basis of the requirement that statutes be of a general character (Judgment No. Pl. US 40/02, The Collection of Judgments and Rulings of the Constitutional Court, Vol. 30, p. 327 and foll.). The supporting points of the argumentation apply to this case as well. In that case, the Constitutional Court recalled the arguments in favor of the general character of statutes, alternatively of legal enactments, which are the following: the separation of powers, equality, and the right to one’s own, independent judge.

45. The first of the reservations to statutes, legal enactments relating to singular cases is the principle of the separation of powers, or the division of the legislative, executive and judicial powers in a democratic, law-based State: „It is the field of law application which presents the greatest obstacles to the adoption of statutes relating to singular cases. The claim to one’s lawful judge and the independence of legal protection exclude the legislature from issuing individual commands, also in fields not protected by means of the principle, *nulla poena sine lege* (in this respect *lex* can be a meaningful manner only if it is a written legal sentence of a general nature).“ (H. Schneider, *Gesetzgebung [Legislation]*, 2nd ed., Heidelberg 1991, p. 32).

46. Under the existing legal situation, the interested persons also cannot obtain judicial protection. Regarding the issue of the exclusion from judicial review in the case of an individualized legal regulation, the Constitutional Court stated, in its above-cited Judgment No. Pl. US 40/02: “An individualized regulation contained in a legal enactment which deprives its addressees of any opportunity to seek judicial review as to whether a particular person has satisfied the general conditions of a normative framework and which lacks transparent and acceptable justification in

relation to the possibility to regulate the matter generally, must be considered to be in conflict with the principle of the law-based state (Art. 1 of the Constitution), of which the separation of powers and judicial protection of rights constitutes an immanent component (Art. 81, Art. 90 of the Constitution).”

47. As regards the availability of procedural protections, the European Court of Justice adopted, in the mentioned cases, a similar approach. As regards the issue of the availability of legal remedies against the decision, the text of the Directive merely provides that applicants should be informed of the legal remedies available. The European Court of Justice deduced therefrom that the applicant must have the possibility to avail itself of remedies ensuring effective legal protection of its rights. Moreover, it did not consider an administrative remedy to be sufficient, rather, it should have the character of judicial review. The Constitutional Court entirely concurs with that interpretation, as it also fully corresponds to the requirements enshrined in Art. 36 para. 2 of the Charter.

48. The same deficiencies of which the European Court of Justice were critical in relation to the Directive are also evident in the provisions under review, § 15 para. 10 of the Act on Public Health Insurance, in relation to the Charter of Fundamental Rights and Basic Freedoms. Setting the specific level at which a medication will be reimbursed by means of a regulation de facto rules out the participation of interested persons in this process, and it weakens the transparency of particular stages and, thereby, the trustworthiness of the entire process. The appropriateness of the specific level of reimbursement for one or another medication should be ensured in the course of an administrative process on the basis of a weighing of the various particular interests, with the opportunity to consider all dissenting views and observations. Above all, the decision on one or another medication should then be reasoned, so that it would be evident why prerequisites for its inclusion into the system of reimbursement from health insurance are better than the prerequisites for some other medications, and how the deciding body dealt with the basic arguments.

49. While it is true that the amendment to the Act on Public Health Insurance, recalled by the Assembly of Deputies in its statement (Act No. 438/2004 Coll. and No. 123/2005 Coll.), introduced into § 15 of the Act, some elements of procedural protection. That still does not mean, however, that such a measure is sufficient in and of itself. After all, it relates solely to the Ministry’s decisions on the inclusion of medicinal preparations onto the list, which for any medicinal preparation is a prerequisite to its being reimbursed from the system of public health insurance (and apparently indicates all medicines on the list will be reimbursed, at least partially), but which is not a decision of direct significance for determining whether a particular medicinal preparation will be fully reimbursed or only in part. It is only at the second step that the decision is made as to the concrete amount by which medicines will be reimbursed from public health insurance. It is an entirely separate measure, separate decision-making, in the case of which the statute does not provide for the guarantee of procedural rights, as is required by Art. 36 paras. 1 and 2 of the Charter.

50. The empowering provision of § 15 para. 10 of the Act on Public Health Insurance infringes the principles described above, and is therefore incompatible

with the principles of the law-based state, and thus in conflict with Art. 36 of the Charter. In this circumstance, the Constitutional Court observes that it is no longer necessary to concern itself with the impact upon the designated legal rules of further constitutionally protected rights, such as, for ex., the right to property, since the above-stated finding, and the conclusion of unconstitutionality corresponding thereto, suffices to derogate the contested provision of the Act on Public Health Insurance.

VII.

51. The Constitutional Court cannot overlook the fact that in the event it annuls § 15 para. 10 of the Act on Public Health Insurance, that portion of the final sentence of § 15 para. 5 of the Act on Public Health Insurance which follows the semicolon and reads, „the level of their reimbursement from health insurance shall be laid down in an implementing regulation,“ would also lose any sort of foundation. Both provisions are so closely connected to each other that the one cannot stand independently of the other.

52. In consideration of the above-stated arguments, the Constitutional Court has, in accordance with § 70 para. 1 of the Act on the Constitutional Court, annulled the provisions of § 15 para. 10 and the final sentence of its para. 5 which follows the semicolon and reads, „the level of their reimbursement from health insurance shall be laid down in an implementing regulation“.

53. In conformity with § 70 para. 3 of the Act on the Constitutional Court, the Constitutional Court also declared, that simultaneously with the annulled statutory provision, the Regulation of the Ministry of Health issued on the basis of the empowerment contained therein lost its validity. At the point in time when the Court decided on the petition, it was Regulation of the Ministry of Health No. 532/2005 Coll. The Constitutional Court has dismissed the proceeding on the petition seeking the annulment of Regulation of the Minister of Health No. 589/2004 Coll., as it lost its validity in the interval between the submission of the petition and the conclusion of the proceeding (§ 67 para. 1 of the Act on the Constitutional Court).

54. Rectification of the existing situation requires a change in the legislative scheme currently in force. The legislature must elaborate an entirely new regime for the compensation of medications from public health insurance funds, one which would also correspond to the principles adumbrated in the reasoning of this judgment. The Constitutional Court is aware of the fact that it is necessary to provide the legislature with sufficient time in which to form and adopt the new legal framework. It therefore decided to postpone, until 31 December 2007, the coming into effect of its annulling judgment.

Notice: Judgments of the Constitutional Court may not be appealed.

Brno, 16 January 2007