

Decision no. 28, dated 27.05.2010

(V - 28/10)

Constitutional Court of the Republic of Albania, consisting of: Vladimir Kristo, President, Kujtim Puto, Xhezair Zaganjori, Petrit Plloçi, Vitore Tusha, Sokol Sadushi, Admir Thanza Sokol Berberi, members with secretary Aldi Çinari, dated 10.12.2009, received in the review hearing on an open court session, issue nr.28/17, belonging to:

APPELLANT: ASSOCIATION OF ALBANIA'S PHARMACEUTICAL DISTRIBUTORS, represented by JD.Vangjel Kosta, by proxy.

INTERESTED PARTIES:

COUNCIL OF MINISTERS, represented by Marsida Xhaferllari by proxy.

MINISTRY OF HEALTH, represented by Sokol Frroku, Andoneta Njehrrrena and Ahmet Hysa by proxy.

SUBJECT: (a) Repeal as incompatible with the Constitution of the Council of Ministers Decision nr.521, dated 13.05.2009 "Regarding the approval of the list of drugs to be reimbursed by coverage from the Institute of Health Insurance and the amount of their price", a key part of the price list for the drugs to be reimbursed under the heading "references".

(B) Suspension of implementation of the Decision of the Council of Ministers nr. 521, dated 13.05.2009, on the repeal of the act subject to this requirement (section "reference price" of the list of medicines reimbursed).

LEGAL BASIS: Articles 11, 17, 131, letter "c", 134, 1 "f" of the Constitution of the Republic of Albania and Articles 27-30, 45, 49-51 of the Law No. 8577, dated 10.02.2000, "For organizing and functioning of the Constitutional Court of the Republic of Albania".

CONSTITUTIONAL COURT,

after hearing the rapporteur Sokol Berberi; the representative of Pharmaceuticals Distributors Association of Albania (SHDFSH¹) who sought the admission of the claim; representatives of interested parties, who sought its abrogation, and discussed the case in its entirety,

NOTED:

I

1. On 13.05.2009 the Council of Ministers (CoM) has approved the decision nr.521 "Regarding the approval of the list of drugs to be reimbursed by coverage from the Institute of Health Insurance and the amount of their price" pursuant to Article 100 of the Constitution of Republic of Albania, Articles 4 and 15 of the Law No. 7870 "On Health Insurance of the Republic of Albania" and Law nr.10025 "On State budget ". This decision approves the list of drugs reimbursed by the Health Insurance Institute (HII) and the extent of price coverage of the reimbursed medicines.

2. On 25.06.2009, SHDFSH, addressed the Constitutional Court with a request to annul the Decision of the Council of Ministers dated 13.05.2009 nr.521, on the act subject to the abrogation of this requirement (under the heading "reference price" of the list of drugs reimbursed) as well as to suspend the implementation of the above act until a final decision of this Court.

3. *Petitioner* contends that:

- The decision which is subject to review violates the principles of freedom of economic activity and proportionality which are protected by Articles 11 and 17 of the Constitution, since the price determined by this decision of the CoM constitutes a

¹*Translator's note: acronym corresponds to Albanian name.*

disproportionate interference and dictates the conditions for unfair economic activity of wholesale trading drugs. Prices set by the Council of Ministers represent a measure of monetary character, which in itself is considered a limitation. Prices set by the decision which is subject to review ensure that some of the drugs will be sold below the cost, while others will be sold at price that does not allow any possibility for planned commercial activity, therefore, creating major difficulties in management of this activity.

- CoM's decision, subject to review, should be suspended until the final decision of the Constitutional Court, after analyzing the facts and bylaws, shows that the implementation of this normative act creates huge difficulties in economic activity and for demanding trade association members and therefore creates consequences regarding what is required by Article 45 of Law No. 8577, dated 10.02.2000 "On the organizing and functioning of the Constitutional Court of the Republic of Albania".

4. Entity concerned, the Council of Ministers requested the rejection of the request, submitting that:

- SHDFSH does not have standing to set in motion the Constitutional Court because the application submitted for review fails to justify the relevance of the matter to SHDFSH's interests and to violations of the rights and freedoms provided in the Constitution. The interest that the applicant should have consists in the violated rights and the actual or potential harm and not the theoretical premises of the unconstitutionality of the law.

- CoM's decision, subject to review, in pursuit of its legal obligations, has not regulated the price of the medicines or set the price of the medicines as alleged in the claim, but has regulated the list of reimbursed medicines and the extent of price coverage for the medicines included in listing. Hence, the purpose of this decision is the reimbursement of drugs, not the evaluation of the sale pricing of medicines. The request presented to the Constitutional Court makes a mistake on the subject. The column, which is part of this decision, sets a reference price on the basis of which value the state agrees to reimburse the price of drugs and the amount paid by the patient. In none of the eight points of the decision is the obligation of pharmacists to trade medicines marketed at the prices specified in the labels attached to it determined.

- The legal framework that determines the price of the medicines is different from the one that the applicant rejects. There is no violation of Article 11 of the Constitution by the decision subject to review because the restriction regarding the price of the medicines is determined by law. The Council of Ministers has the right to determine the price of the medicines under the Law nr.9323, dated 25.11.2004 "On drugs and pharmaceutical services" (Law on drugs). CoM, with the decision No.56 dated 28.01.2005, has determined that the conversion is done according to the average exchange rate announced by the Bank of Albania. In drafting of the decision subject to review the average exchange rate is kept in consideration for the semiannual period, according to the official announcement of the Bank of Albania. Due to exchange rate fluctuations, the decisions that predict the extent of reimbursement from the state, are approved each year by the Council of Ministers.

5. Entity concerned, the Ministry of Health, submitted that the request should be rejected because:

- Article 50 of the drug law stipulates that price of drugs on the market is controlled, based on CIF import prices and the price of manufacturing drugs produced in the country. The profit margin of manufacturing drugs on the market and prices on the drugs reimbursement list are determined by the decision of the Council of Ministers. The Commission on the price of drugs, which functions as a permanent unit in the Ministry of Health, approves each calendar year the maximum CIF prices (in euros or dollars) for imported drugs and the price of manufacturing in domestic currency (lekë) for locally produced medicines. CIF prices in Albania are declared by the manufacturer or its representative by 31 October of each year.

- CoM's decision, subject to review, issued pursuant to articles 4 and 15 of Law No. 7870, dated 04.13.1994 "On health insurance in the Republic of Albania", as amended (the health insurance law) approved the list of drugs that will be reimbursed during 2009. Every year there emerged a CoM decision to this effect. Such a decision is also expected to be approved for 2010. The method for preparing this list and the formula for how prices will be calculated in this list are defined in the law of the medicines.

II

A. Regarding the legitimacy of Pharmaceuticals Distributors Association of Albania to put in motion the Constitutional Court by the scope of application

6. The Constitutional Court (the Court), in its jurisprudence has interpreted the constitutional criteria for legitimizing organizations as entities that can put it in motion (see the Constitutional Court decision No.9/2007 No.11/2007, No. 35 / 2007; nr.41/2007; nr.9/2008, no.12/2009). Associations or other organizations defined in Article 134, paragraph 1, letter "f" of the Constitution, as subjects who exercise a conditional right to address the Court, only have constitutional standing for issues related to their interests (see Constitutional Court Decision No. 35, dated 10.10.2007). They have the obligation of proving the necessary direct and individualized relationship that should exist between the legal activity they perform and the constitutional issue raised. The interest required to act should be secure, direct and personal.

7. SHDFSH (the Association of Pharmaceutical Distributors of Albania) is a legal entity registered in the District Court of Tirana with decision No.4199 from 26.12.2000. Members of this association are companies that carry out economic activity on the pharmaceutical market in Albania. The Charter of this Association provides, inter alia, that its main goal is "... protection and preservation of the economic interests of its when dealing with other state organizations both nationally and outside the country". Thus, this Association is an organization that protects the economic interests of its members, legal persons that exercise economic activity in the relevant field. The legal framework pertaining to the price ranking of the drugs constitutes the main purpose of their activity and is presumed to have a direct impact on the economic activity of members of the association. This interest is now raised in front of the Court using the argument that the CoM decision is allegedly unconstitutional and the interest for its standing at the Constitutional Court is considered to have been conceived at the moment when that legal act entered into force, with its publication in the Official Journal.

8. Based on the above, the Court considers that the CoM's decision which is subject to review has a direct link with the economic activity of the claimant members of

the association, hence the association has standing to oppose this CoM decision (on the premises described in the subject of this application), and thus is authorized to act regarding the alleged violations of article 11/3 and 17/1 of the Constitution.

B. Regarding the request for suspension of CoM Decision which is subject of demand

9. The Court took the application into consideration prior to suspension of the implementation of the ***CoM Decision*** dated 13.05.2009 nr.521 regarding the repeal of the act subject to this requirement (section "reference price" of the list of reimbursed medicines). On the basis of Article 45 of the Law No.8577, dated 10.02.2000 "On the organization and functioning of the Constitutional Court of the Republic of Albania", the application was denied. The Court found no convincing arguments regarding the possibility that state interests, social or individual, would be endangered as a result of the immediate implementation of this decision.

C. Regarding the allegation that the decision which is subject to review violates the constitutional principle of freedom of economic activity

10. Petitioner alleges that the CoM decision which is subject to review violates the principle of freedom of economic activity and the proportionality protected by Articles 11 and 17 of the Constitution, arguing that the price stated in the decision subject to review constitutes a disproportionate interference with the Council of Ministers as conditions dictate the unfair economic activity of trading in wholesale drugs. Prices set by public authorities such as the Council of Ministers represent a measure of monetary character, which in itself is considered a limitation.

11. The Court reiterates that freedom of economic activity, guaranteed by Article 11 of the Constitution means mainly the right to contract, individually or collectively, freely and on the basis of the will, the right to choose activities that the individual wishes to exercise, the right to choose a job of one's preference, etc. This freedom includes all rights associated with the production, distribution or consumption of goods and services. The highest form of economic freedom means the right to property, freedom of movement, labor without any restrictions, capital and goods, that individual has the right to work, produce, consume and invest in any way that he pleases and this freedom

should be protected by the state. Freedom of economic activity in itself contains many rights and freedoms, such as freedom of business or the ability to create and terminate an enterprise, the freedom of trade or lack of barriers and services related with the import and export of goods and services, monetary freedom as a measure to ensure price stability, fiscal freedom over income, whether with respect to the individual or with respect to business in particular, property rights as the ability of individuals to accumulate, possess, and dispose of items free from state interference, freedom of investment and freedom of movement of capital, especially foreign capital, financial freedom and independence from state control, freedom of work to interact without restriction by the state (*see the decision of the Constitutional Court. No.10, dated 19.03.2008*).

12. The Court has expressed that freedom of economic activity implies the obligation of the state, through legislation, to intervene in the regulation of this freedom in order to ensure, in addition to freedom of economic activity, the principle of the social state and the common good. This legislators' obligation to adjust is expressed through the issuance of specific legal norms, by which the disciplining the free exercise of economic activity in certain sectors or areas is intended. Only the state can accurately achieve the optimum environment environment for the exercise of this personal freedom, so it should be seen as a regulator in order to protect the market from distortions that the free development of economic activity can naturally carry with it. (*See Decision No. 10, dated 19.03.2008 of the Constitutional Court*).

13. The Court has clarified the criteria under which the state can intervene to regulate the exercise of freedom of economic activity under this Article of the Constitution. It has expressed that, given the structure of the Constitution, the specific Article 11 paragraph 3 is that it is not included with the group of other rights and freedoms, but with the fundamental principles on which the organization and functioning of the state is based.

14. The Constitutional Court has assessed whether or not there exists a violation of economic freedom, referred to by the content of Article 17/1 of the Constitution, which extends to all the rights and freedoms provided for in it, according to which, "... The restrictions of the rights and freedoms stipulated in this constitution may be established

only by law, for public interest or for the protection of the rights of others. The restriction must be proportionate to the situation that has dictated it." This provision, other than public reason, which is found at Article 11/3, contains the obligation to respect the other criteria, such as the restriction to protect the rights of others and the existence of the correct ratio between the limitation and condition that dictates it. The known principle of proportionality implies that legislators intervening to limit a right or freedom be given adequate tools to respond to the goal to be achieved (*see Constitutional Court Decision No. 10, dated 19.03.2008*).

15. The Court has previously explained the meaning of the expression "only by law". The phrase "only by law" means that in the event the restriction of a right which is provided by the Constitution is needed, the assessment is solely at the discretion of the Assembly and not of the other legislatures, including the Council of Ministers. This conclusion is achieved by referring to the word "only" mentioned in Articles 11/3 and 17/1 of the Constitution. The use of this word is not accidental, but used with the intention of showing that such restrictions can not be imposed by any act other than the law. The Constitutional Court determined that the phrase "only by law" refers to the competence of the legislature and the use of other acts to regulate such relations, violates the powers of this body (*see Constitutional Court Decision No.20, dated 11.07.2006*).

16. Regarding the conditions established in Article 17/1 and in relation to Article 11/3 of the Constitution, the Court considers that the criteria for restriction of the public interest or protection of the rights of others and the principle of proportionality of legislative intervention, which as a rule, subordinate and complement one another. Regarding the public interest, the Constitutional Court has confirmed that legislators' initiative to restrict the freedom of economic activity is reasonably acceptable. This restriction is placed to regulate the market or the interests of a welfare state. These legislative measures could be various in nature and can even have monetary character, e.g., introduction of taxes and fees which are considered as limitation. In general, the guarantee that the individual is free to choose his desired field of activity (his preferred economic activity) and to implement his ideas in such selected economic activity, is considered sufficient. What matters is that the core activity of the individual is

not violated to the extent that its delivery is brought under question (see Constitutional Court Decision No. 10, from 19.03.2008).

17. Based on the above standards, the Court first assesses whether the CoM decision which is subject to review restricts the economic freedom of the members of the claimant. Subsequently, the assessment considers elements, whether the alleged restrictions are made according to the criteria defined in the Constitution, thus, by law, in the public interest or for the protection of the rights of others and, in proportion to the situation that has dictated it.

18. The decision which is subject to constitutional review was issued pursuant to Articles 4 and 15 of Law No. 7870 dated 04.13.1994 "On health insurance in the Republic of Albania". In Article 4, paragraph 3 of the Law it is provided, inter alia, that measure of the coverage of major drug price is determined each year by the Council of Ministers. Article 15 of the law provides that the list of drugs reimbursable by HII with the CoM decision as previously defined by HII. Regulation and control over the prices of the drugs is regulated by article 50 of Law nr.9323 dated 12.25.2004, "On Drugs and Pharmaceutical Service," as amended, which provides that the price of drugs in the market is controlled and based on CIF import prices and prices based on the fabrication of locally manufactured drugs; Drug price control in the market is carried through the fabrication margins of trading that are defined by the Council of Ministers; prices of drugs reimbursement list are determined by the Council of Ministers.

19. Based on the foregoing, the Court finds that the method of preparing this list and the formula for how will prices be calculated on this list are defined in the law for drugs and CoM Decision 504 dated 8.08.2007 "On establishment and the functioning of the price of drugs" and the CoM Decision no. 56 dated 28.01.2005 "On the determination of margins of fabrication and marketing of drugs." The Drug Pricing Committee of the Ministry of Health approves each calendar year the maximum CIF prices (in euros or dollars) for the drugs of import and fabrication prices (in Lek) for locally manufactured drugs.

20. The Court notes that the decision subject to review is an act issued in support of the law on health insurance, as amended, and the state budget of 2009. It defines margins differentiated by the list of drugs which are reimbursed on the basis of the

mechanism / formula determined in the above mentioned acts. In these conditions the Court considers that, if there is restriction on liberty of economic activity, this restriction has been adjusted by the law on health insurance and drugs, and not by the legal act which is subject to review. These two laws are not subject to the constitutional review.

21. Moreover, the petitioner does not have standing to seek constitutional control of the two laws mentioned above. In Article 50 of the LAW 8577, dated 10.02.2000 "On the organization and functioning of the Constitutional Court", it is provided that the requirements regarding the review of the compatibility of a law or other normative acts with the Constitution or with international agreements must be filed within three years from entry into force. The Court notes that the health insurance law and the law on drugs have entered into force earlier than three years before the date of filing of the application which is subject to the Constitutional review, and, in these conditions, the three years period provided for in the law for Constitutional Court has passed.

22. Based on the foregoing, the Court concludes that the applicant's claim that the Decision nr.521 dated 13.05.2009 CoM violates the freedom of economic activity disproportionately is unfounded and therefore should be rejected.

FOR THESE REASONS:

Constitutional Court of the Republic of Albania, based on Articles 131, the letter "c" and 134, paragraph 1, letter "f" of the Constitution, and Article 72 of Law No. 8577, dated 10.02.2000 "On the organization and functioning of Constitutional Court of the Republic of Albania ", unanimously,

DECIDED:

- Rejection of the application for invalidation as incompatible with the Constitution of the Decision of Council of Ministers nr.521, dated 13.05.2009 "Regarding the approval of the list of drugs to be reimbursed by coverage from the Institute of Health Insurance and the amount of their price", a key part of the price list for the drugs to be reimbursed under the heading "references".

This Decision is final, irrevocable and shall enter into force on the day of its publication in the Official Journal.