HEALTH LAW
SOME PRACTICAL ASPECTS OF HEALTH LAW MATTERS REFLECTED IN CONTENTIOUS ADMINISTRATIVE

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Abstract

The present paper set out to analyze certain aspects encountered in the legal practice of contentious administrative courts in the field of health law, with particular approach of specific issues concerning the manner in which the patient's rights are recognised and respected and valued. Correspondingly, the paper debates matters related to the competent public authorities' ability to resolve applications on the recognition of certain rights and at the same time the study treats controversial aspects or aspects regarding non-unitary practice in the field of contributions to the national health insurance fund.

Key Words: *Administrative contentious / patient's rights / social health insurance*

JEL Classification: *[K23]*

1. Preliminaries

In health law we can find, among others, several concepts, such as for example: health, right to health, health law.

Working with such concepts requires some terminological distinction especially because their roots are reflected in the word "health".

Thus, in the definition given by the World Health Organization, *"Health is a fully favorable state, physically, mentally and socially, and not merely the absence of disease or infirmity" and the "ability to lead a productive life, socially and economically".*

Therefore, health is not itself a legal concept but is rather related to the human condition.

The right to health (health protection, according to art. 34 of the Romanian Constitution) is regulated in the law as a fundamental human right.

From the perspective of international law and human rights, especially in the sphere of European human rights, it is important to note that health as an inherent attribute of the human person is covered by and thus guaranteed in art. 2 of the European Convention on Human Rights and Fundamental Freedoms, in that in order to protect health Member States have certain positive obligations.

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Health law is nothing else but all the legal rules governing the **system** (the ***field***, according to the terminology used by art. 1 of Law 95/2006) on health: health care, medical insurance, malpractice, etc.

The administrative court is, according to the legal definition contained in Art. 2 para. 1 letter f) of the Organic Law of administrative disputes no. 554/2004 *the settlement by competent administrative courts under organic law of disputes in which at least one party is a public authority, and the conflict was born either by issuing or concluding, as appropriate, an administrative document, within the meaning of this law, either by non-settlement in the legal term or the unjustified refusal to address a request regarding a legitimate right or interest.*

In other words, the contentious administrative matters are a form of control of public administration conducted by administrative courts.

As said, judicial supervision, as judicial function[1], takes place both through common law litigation, conducted by specialized administrative courts and through an exception contentious way, conducted by the ordinary courts through the parallel appeal institution[2].

Therefore, we highlight below some practical aspects of health law matters reflected in the administrative jurisdiction.

The present study will focus mainly on two main axes: the power of health insurance houses to issue administrative tax documents to determine the contributions owed to FUNASS (Unique National Health Insurance Fund) and patient's rights, especially refusal to recognize the right to settle purchases of drugs or medical devices.

2. Jurisdiction of health insurance houses to issue administrative acts establishing tax contributions due to FUNASS (Unique National Health Insurance Fund)

As a starting point in this analysis we must primarily include the provision regulated in art. 35 para. 1 of CNAS President Order no. 617/ 2007[3] approving the Norms concerning the supporting documents for the acquisition of the quality of

[1] It should be noted that the government knows several forms of control, among which mainly judicial and administrative control. While the administrative control is carried out by administrative authorities as provided by law, judicial control is conducted solely by courts which do not state *ex officio* but only upon notification of legal persons specifically provided by law while the administration can carry out a spontaneous control, unplanned, or after a referral; always the court rules according to the law and when needed through enforcement, while the administration generally has an opportunity control right based on a certain discretion margin on the public administration. For more information, see Ch. Debbasch, Fr. Colin, *Droit administratif*, 11e édition, Economica, Paris, 2014, p. 512.

[2] O. Puie, *Tratat teoretic şi practic de contencios administrativ (Theoretical and practical treaty on administrative courts),* vol. 1, Universul Juridic Printing House, Bucharest, 2015, p. 10.

[3] Published in the Official Gazette of Romania, Part I, no. 649 of September 24, 2007.

insured person, or insured without paying the contributions, as well as the application of enforcement measures to collect amounts due to the Unique National Health Insurance Fund.

This order was drawn up pursuant to the provisions contained in Title VIII - Health Insurance - Law no. 95/2006.

According to art. 35 para. 1 of the aforementioned Order: *Pursuant to art. 215 par. (3) of the Law and art. 81 of the Code of Fiscal Procedure, for payment obligations to the Fund of individuals who are insured based on an insurance contract, other than those for which revenue collection is done by ANAF, the debt is, where appropriate, the declaration referred to in art. 32 para. (4), tax decision issued by the competent authority of CAS, and judgments on debts owed to the Fund. The tax decision may also be issued by the competent authority of CAS based on information received from ANAF as protocol.*

In this regard, through the provision of Order no. 617/2007, the competent authority of CAS was empowered to issue a tax decision based on information received from ANAF as protocol, and it was actually achieved in practice during the period: 24.09.2007 - 04.04.2014 up to the actual date of cancellation of the provision in art. 35 para. 1 which occurred as a result of Civil Sentence no. 835 of 08.02.2012 of the Bucharest Court of Appeal[4].

Subsequently, Order no. 617/2007 was directly and entirely repealed by art. 3 of CNAS President Order no. 581/2014[5] approving the Methodological Norms for establishing the supporting documents on receiving the quality of insured person.

Finally, also related to the competence of health insurance houses to issue administrative acts establishing tax contributions due to FUNASS it be noted that by GEO no. 125/2011 amending and supplementing Law no. 571/2003 regarding the Fiscal Code, some conceptual changes were made, inter alia, regarding health fund administration and also the transfer of competence regarding the administration of compulsory social security contributions was put in discussion, a concept which was then preserved in the new tax rules[6].

In this respect, art. V of GEO no. 125/2011 stipulated that with effect from 1 July 2011 the power to manage compulsory social health contributions belongs to ANAF. In this respect, art. V para. 2 of this emergency ordinance set the rule that jurisdiction for managing social security contributions owed by individuals for

[4] This judgment was published in the Official Gazette of Romania, Part I, no. 243 of 04/04/2014 as an effect to art. 23 of Law no.554/2004.

[5] Published in the Official Gazette of Romania, Part I, no. 685 of September 19, 2014 effective from the date of publication according to art. 12 of Law no. 24/2000.

[6] See Chapter III norms - *Social health insurance contributions due to the budget of the Unique National Health Insurance Fund,* Title V - *Compulsory social contributions* of Law. 227/2015 regarding the Fiscal Code, published in the Official Gazette of Romania, Part I, no. 688 of September 10, 2015.

income for fiscal periods prior to 1 January 2012 and the period 1 January to 30 June 2012 in respect of social security contributions for the year 2012 and also for settlement of appeals against administrative acts that set the amounts, belongs to social insurance houses according to specific legislation applicable to each period.

There is an exception from this rule in the third paragraph, stating that in the conduct of a tax audit for the periods prior to 1 January 2012, establishing social contributions and the settlement of appeals against administrative acts belongs to tax authorities.

This legislative array and the changes made over time have given rise to a rich jurisprudence that we will selectively review below.

Under the influence of art. 35 para. 1 of Order no. 617/2007 and Protocol no. P5282/26.10.2007/95 896 of 30.10.2007 concluded by CNAS and ANAF and the addendum no. 1 (181797/13.04.2009/801 320/09.04.2009) it was established by law that the territorial level houses have jurisdiction to issue tax debt[7]. To argue this we refer to Decision no. 3878 of September 27, 2010 issued by the ICCJ - Administrative and Fiscal Litigation Section, which examined the illegality exception of said text.

Though the decision mentioned, followed a series of similar decisions, that have shaped a constant legal practice in ICCJ, it was stated that:

„*The provisions of art. 35 of the Norms concerning the supporting documents for the acquisition of the quality of insured person or insured person without paying contributions, are legal, and so are those on the application of enforcement measures to collect amounts due to the Unique National Health Insurance Fund approved by Order no. 617/2007 of the President of the National Health Insurance, provisions under which the Health Insurance House (CAS) has legal empowerment to issue a tax decision, which at maturity acts as enforcement, under which the offenders can be prosecuted.*

These provisions comply with both the legal framework established by Law no. 95/2006, for the execution of which Order no. 617/2007 was issued, and the general legal framework, as long as, strictly on payment obligations to the Unique National Health Insurance Fund, under the powers conferred to health insurance houses to apply enforcement measures, they include those powers to issue executive orders, under the conditions and in compliance with art. 141 from Government Order no. 92/2003 regarding the Fiscal Procedure Code."

Following this decision, and the like, the practice of the Cluj Court of Appeal and other administrative courts in the country, was to recognize the

[7] Cluj Court of Appeal, Civil Division II., adm. and fisc., civil decision no. 4395 from April 18, 2013.

competence of county health houses for issuing tax debt for determining contributions to the *Unique National Health Insurance Fund*[8].

Canceling art. 35 of CNAS President Order no. 617/2007 subsequently gave rise to the problem of the effects of Bucharest Court of Appeal ruling on the disputed documents and pending litigation, still unresolved.

In order to interpret and apply domestic law in such situations ICCJ was referred in the procedure for obtaining a preliminary ruling to resolve a question of law under art. 519 et seq. from the Civil Procedure Code.

In this respect, decision no. 10/2015 issued by ICCJ - Bench responsible for solving the issues of law in the matter of administrative disputes[9] decided that: "*The provisions of art. 23 of the Law no. 554/2004, as amended and supplemented, shall be construed as meaning that the final judicial decision annulling all or part of an administrative act, normative in nature, has legal effect on individual administrative acts issued pursuant thereto which, at the date of publication of the judgment of annulment, are challenged in pending cases before courts."*

This decision and the manner of interpretation has created a rich jurisprudence in the matter analyzed, considering that the provisions of art. 35 para. 1 of Order no. 617/2007 of the CNAS President are the reasons for issuing tax-administrative acts contested, so because the legal text on which they were issued was canceled, the consequence is that the decision to cancel has effects also on pending cases under Decision no. 10/2015 of the ICCJ, meaning that administrative acts are void on the grounds that the administrative authority which issued them no longer has the legal competence to issue them[10].

In this context, judicial practice takes into question the effects of a judgment to cancel the provisions of art. 35 para. 1 of the Order of the President of the National Health Insurance House no. 617/2007 on tax decisions issued before the irrevocable publication of the judgment and the competence of C.A.S. to issue tax decisions regarding the legal relations arising prior to the publication of the judgment in the Official Gazette no. 243/4 April 2014, in the context of art. V para. 2 and 7 of Chapter III of Government Emergency Order no. 125/2011.

This issue was resolved at the meeting of representatives of the Superior Council of Magistracy with the presidents of the administrative and fiscal

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[8] It should be noted however that in the literature, such a judicial practice has been questioned and the justice of decision no. 3878 of 27 September 2010 issued by the ICCJ was criticized - Administrative and Fiscal Litigation Section. See in this regard, C.F. Costas, *Health insurance. Cluj Court of Appeal illegality of decisions subsequent to September 17, 2013*, which can be accessed on the legal portal at the web address: http://www.juridice.ro/317409/asigurari-de-sanatate-nelegalitatea-hotararilor-curtii-de-apel-cluj-ulterioare-datei-de-17-septembrie-2013.html.

[9] Published in the Official Gazette of Romania, Part I, no. 458 of June 25, 2015.

[10] In this regard, see Cluj Court of Appeal, Section III adm. and fisc. department, civil decision no. 448 of 10 December 2015, no. 5133 of 09.09.2015, no. 24 of 13.01.2016, no. 143 of 25.01.2016, no. 251 of 17.02.2016, no. 59 of 18.01.2016 and no. 428 of 09.12.2015.

departments from the High Court of Cassation and Justice and the Courts of Appeal of Suceava during 23 to 24 October 2014[11] where it was held in essence that... *even in the context of cancellation of the provisions of art. 35 para. 1 of the Order of the C.N.A.S. President no. 617/2004, until June 30, 2012, inclusive, health insurance houses were given the right, under art. V para. 2 of Chapter III of G.E.O. no. 125/2011 to issue tax decision and subsequently to settle administrative complaints made against these decisions. The conclusion is also supported by the fact that the deadline set by the provisions of art. V para. 10 of G.E.O. no. 125/2011, in which social insurance houses were required to submit to A.N.A.F. a copy of the titles by which social contributions payable by individuals under par. 2 were individualized, was extended successively through art. III of G.E.O no. 71/2013 through art. III of G.E.O no. 115/2013 until 30 June 2014, inclusive.*

In view of the above, recently the Court of Justice of the European Union (CJEU) ruled in Case C-201/14 Bara and others by the judgment of October 1, 2015[12]. By this ruling it was decided that: *Articles 10, 11 and 13 of Directive 95/46/EC of the European Parliament and of the Council of October 24, 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data must be interpreted as precluding national measures such as those at issue in the main proceedings, which allow a public administration authority of a Member State to submit personal information to any other authority of public administration and further process this information, without the persons concerned beening informed of this transmission or processing.*

This decision was based on a complaint filed by the Cluj Court of Appeals through the conclusion of March 31, 2014 in the case no. 740/33/2013 which focused on, inter alia, the annulment under action of art. 35 para. 1 of Order no. 617/2007, and Protocol no. P5282/26.10.2007/95 896 of 30.10.2007 concluded by CNAS and ANAF and the addendum no. 1 (181797/13.04.2009/801320/09.04.2009).

After the Decision given in the Bara and Others case and after the case was subject once more to a ruling, by civil sentence no. 64 of December 14, 2015[13] the Cluj Court of Appeal (CJUE) cancelled the protocol and addendum mentioned above. The court noted, with reference to the CJUE judgment in the Bara case, and thus its subject matter, in essence, that the contents of this Protocol and its addenda unequivocally shows that it does not contain a clause on informing individuals whose data are processed, notification that should be made by the

[11] For details see document on page 11 point 12 at the following address: http://www.inm-lex.ro/fisiere/d_758/Minuta%20intalnire%20contencios%20administrativ%20Suceava,%20octombrie%202014.pdf.

[12] For details: http://curia.europa.eu/juris/document/document.jsf?docid=168943&doclang=RO.

[13] The Decision is not final. It has been appealed and, at the date the paper was written the file was subjected to the filtering procedure of the High Court of Cassation and Justice. For details see: http://www.scj.ro/1094/Detaliidosar?customQuery%5B0%5D.Key=id&customQuery%5B0%5D.Value=3300000000059933.

authority carrying out this data, i.e. CNAS, as required by art. 11 of Directive 95/46/EC. The first instance court also held that violation of these provisions by the contents of this protocol and processing of plaintiffs' income by CNAS without their prior notification is determined by CJUE in the judgment at para. 42-44, paragraph 45 indicating that there is no situation exempting authority from fulfilling this obligation as was noted in the case of the information covered by art. 10 of the Directive.

Regarding the cause Bara and others, in the judicial practice there is the question of whether this is grounds for revocation of administrative-tax acts issued by the tax authorities after notary offices forward information and personal data with reference to income from real estate transactions.

Without a unified guideline in addressing this issue, we believe that the answer is negative. Thus, the judgment of the ECJ in Case C-201/14 (Bara and others) offers an interpretation of Articles 10, 11 and 13 of Directive 95/46, meaning that they preclude national measures such as those at issue in the main proceedings, allowing a public administration authority of a Member State to submit personal information to any other public administration authority and process this information, without the persons concerned beening informed about this transfer or this processing.

In a subjective administrative action based on art. 1 paragraph (1) and art. 8 paragraph (1) of Law no. 554/2004, the administrative court vested with the merits of the case has the opportunity to check - the whole context of the evidence - if the person concerned has suffered an injury generated by the transmission of personal data and their processing without being informed, precisely whether the individual administrative act that he challenged was based solely on that data transmitted contrary to the Directive.

Only to the extent that such injury is to be proven (i.e. incorrect or incomplete data were submitted) this may possibly be retained or qualified as a reason of illegality of the contested administrative measure that will be investigated case by case.

The fact that the public authority has transmitted personal data to another public authority under which they issued an individual administrative act is not *per se* a reason of illegality inferred solely from the effects of the resolution of interpretation of data given by CJUE in the case Bara and others.

3. Patient rights, in particular the refusal to recognize the right to settle purchases of drugs or medical devices or other services or treatments

A first issue concerning patients' rights with regard to case law, in particular the Bucharest Court of Appeal, is related to determining whether the condition laid down in art. 1 and following of Law no. 554/2004 is met, in terms of injury, for individuals - patients - acting under CNAS, the Ministry of Health and the

Romanian Government in order to incorporate certain drugs specifically mentioned in the List, including the international common names for medicinal products for insured persons, with or without personal contribution, based on a prescription, in the health insurance system, and the international common names for medicinal products granted under national health programs.

Thus, in one approach[14] there was an affirmative answer, while in another decision a contrary solution was put into discussion.[15]

A novel approach in this regard was made by the brief procedure of the presidential ordinance[16] which first established that the application for presidential ordinance is admissible because it is not a measure that conflicts with the provisions of Law no. 554/2004, so that the application cannot be rejected as inadmissible *de plano,* but it is necessary to analyze the legal requirements laid down in art. 966 of the Code of Civil Procedure. Given the request for a presidential ordinance, the court held, essentially, that the legal requirements are met, meaning that there is semblance of law in favor of the plaintiff: the urgency is given by the fact that it was proven that although the plaintiff suffers from chronic illnesses, the medicines listed and prescribed by the specialist from the current list of medications which are provided by the system of health insurance do not work, that the new medicines prescribed which are the subject of the application, not included in the list, have no positive effect, that given the lack of prescribed medication and taking into account the severity of the plaintiffs' diseases, their very right to life is endangered, a right guaranteed in the register of human rights at a constitutional and conventional level; the temporary nature of the measure sought is determined by the time limits, i.e. the resolution of the merits of the case pending before the Bucharest Court of Appeal, and in terms of merits, the court held that the plaintiff's claim have a semblance of rationality. In this regard, it held, in essence, that the relevant administrative authorities have not taken measures to transpose the obligation in art. 6 of Directive 89/105/EEC of December 21, 1988 to adopt a law providing such criteria where a new drug is included in the list of drugs covered by the health insurance system and a period of 180 days for analyzing requests for inclusion of medicines in this list.

It should be noted that the legal state envisaged by this judgment is not the same now, but the case present is important in terms of its originality within the scope of administrative litigation and the argumentative construction.

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[14] Bucharest Court of Appeal, Section VIII adm.-tax department, civil sentence no. 1600 from June 5, 2015.

[15] Bucharest Court of Appeal, Section VIII adm.-tax department, civil sentence no. 2407 from July 14, 2015.

[16] Andrei Pap, *CAB. Authorities' obligation to provide free medicines against cancer. Note to sentence no. 1950/18.06.2014*, accessible on juridice.ro at website: http://www.juridice.ro/cab-obligatia-autoritatilor-de-a-asigura-gratuit-medicamente-contra-cancerului-nota-la-sentinta-nr-195018-06-2014.html.

As for the current regulatory framework in the matter, it should be noted that the Government adopted on May 13, 2014 Emergency Ordinance no. 23 which was amended and supplemented by Law no. 95/2006 on healthcare reform and amendment of some health laws[17] in that, inter alia, after art. 232 a new article no. 2321 was introduced which provides: "*Criteria for assessing healthcare technology, the documentation to be submitted by plaintiffs, the methodological tools used in the evaluation process on including, expanding indications, non-including or excluding drugs in/from the List of the common names for medicinal products for insured persons, with or without personal contribution, based on prescription, in the health insurance system, and the common names for medicinal products granted under national healthcare programs are approved by the Health Minister, on the proposal of the National Agency for Medicines and Medical Devices. Assessment methodology including, expanding indications, non-including or excluding drugs in/from the List of the common names for medicinal products for insured persons, with or without personal contribution, based on prescription, in the health insurance system, and the common names for medicinal products granted under national healthcare programs, as well as ways of attack are approved by the Health Minister, on the proposal of the National Agency for Medicines and Medical Devices."*

It is worth mentioning that in the motivation of the issue of the emergency ordinance, the Government noted, inter alia, that legislative intervention is determined not only in order to ensure the primary framework for transposing Directive no. 89/105/EEC of December 21, 1988 on the transparency of measures regulating the pricing of medicinal products for human use but also their inclusion in the scope of national systems of health insurance, and also to avoid triggering the infringement procedure, and to avoid imposition of pecuniary penalties against Romania and, what is more important in this analysis, the argument that the justification of the regulation is necessary *in view of the fact that without these regulations Romanian patients cannot have access to new treatments, vital to their life and health, and it is therefore necessary to take swift measures to eliminate disturbances which may be caused by applying the Directive, in order to prevent the irreversible deterioration or degradation of health, especially for patients who depend on access to new drugs, being necessary to limit the destructive effects on the general health of the population.*

In this respect, art. II of the Emergency Ordinance stipulated that for 2014, the revaluation of drugs from the List of the common names for medicinal products for insured persons, with or without personal contribution, with

[17] Published in the Official Gazette of Romania, Part I, no. 359 of May 15, 2014. The Government Emergency Ordinance no. 23/2014 was subsequently approved as a complement to a legal text that has no bearing on this analysis, by Law no. 140/2014 published in the Official Gazette of Romania, Part I, no. 774 of October 27, 2014.

prescription, in the health insurance system, as well as the common international names for medicinal products granted under national health programs, as provided in art. I para. 3, is finalized until October 30, 2014.

In view of art. 232^1 introduced in Law no. 95/2006 as an effect of G.E.O. no. 23/2014 by Order no. 861 of July 23, 2014[18] issued by the Health Ministry, the following were approved: criteria and methodology for evaluation of health technologies, the documentation to be submitted by plaintiffs, the methodological tools used in the evaluation process on including, expanding indications, non-including or excluding drugs in/from the List of the common names for medicinal products for insured persons, with or without personal contribution, based on prescription, in the health insurance system, and the common names for medicinal products granted under national healthcare programs and ways of attack.

Annex II to this Order in Chapter II regulated the appeals of assessment decisions on health technology regarding including, expanding indications, non-including or excluding drugs in/from the List.

The content of this regulation, at first glance, seems to show that only the holder of the marketing permit may appeal the decision issued, but it is preferable, in our view, that in the absence of such an action on his part or when the procedure established by decree on evaluating new medicines is hampered with important consequences in patient healthcare, the patients be recognized their right to challenge the acts of the procedure[19].

With regard to the rights of the patient, it is noted that in a case[20] there was the question of whether the territorial health insurance house is competent to recognize – for the patient benefit - the right to free healthcare. In fact, it held that the plaintiff, as a person with refugee status on ethnic grounds, enjoys the rights conferred by Law no. 180/2009, respectively art. 5 paragraph 1 letter a) on healthcare and medicines, free of charge and with priority, both in the outpatient system and during hospitalization. A hospital unit, through its physician, prescribed medication to the plaintiff that was not in the approved list and

[18] Published in the Official Gazette of Romania, Part I, no. 557 of July 28, 2014.

[19] This goal will be best seen in the legal practice based on actual data of the case, although, as expected, the right to appeal - both administratively under the Order and in administrative courts - formally belongs to the holder of the marketing authorisation. However, we believe that the right of access to justice cannot be restricted or regulated expressly by *secundum legem* administrative legal acts even if they are normative, for, on the one hand, according to art. 126 par. 2 of the Constitution, the jurisdiction of the courts and the judging procedure shall *only* be stipulated by law and, on the other hand, according to art. 126 par. 6 in connection with art. 52 of the Constitution and art. 1 of Law no. 554/2004, judicial review of administrative acts of public authorities, in administrative courts, is guaranteed, excluding those relating to the relationship with Parliament and the military command acts.

[20] Cluj Court of Appeal, Section II adm.-tax department, civil sentence no. 195 from January 13, 2012.

recognized by the health insurance system and so these medications cannot be settled from the health insurance fund.

The Court held that the powers of the National Health Insurance House and county health insurance houses are covered by the provisions of art. 270 and 271 of Law no. 95/2006 and that among them we cannot find the power to issue certificates certifying that an insured person would be entitled to receive free medical assistance and medicines because this right may be exercised only under Law no. 95/2006 and secondary legislation. It was further noted that, in accordance with art. 217 and 218 of Law no. 95/2006, the people insured benefit from healthcare under the multi-annual framework contract. Also, in this context, it was stated that the defendant is required only to certify the quality of the plaintiff on the basis of its records, not to recognize his right to free healthcare, concluding that the appellant's claims, according to which he would benefit from free medicines without restriction or conditioning, are erroneous and contrary to the legal provisions previously cited, which state that this right can be exercised only under the conditions of the framework contract on the conditions for granting medical assistance within the social security health system, response that was also communicated by the defendant prior to the referral to the court.

In another case[21], the question of the legal status of settlement of the cost of treatment abroad was questioned, considering that the surgery abroad was launched at the initiative of the insured person, without there being an emergency and without prior approval from CAS, which keeps the records, under the scope of art. 6, 8 of Health Ministry Order no. 729/2009 without bringing CNAS to trial and without the existence of the approval issues by it.

In fact, it was noted that the medical documents submitted on probation showed that on June 9, 2008 the plaintiff underwent surgery abroad on his right knee. For the situation in question the provisions of Order no. 729/2009 apply, approving the Methodological Norms on the repayment and recovery of the cost of healthcare provided under the provisions of international health documents to which Romania is part of. Art. 8. para. 1 of the Methodological Norms stipulates: "*In circumstances where an insured person in the system of health insurance in Romania goes to a Member State of the European Union in order to receive medical treatment without the prior approval of the health insurance house where he/she is registered as an insured person, he/she pays the cost of medical services provided*." After analyzing the procedure for reimbursement of expenses incurred by the insured person, Romanian citizen, abroad, described in art. 8 of the law previously mentioned, the trial court concluded that the legal nature of the approval to be expressed by CNAS is obligatory, and the defendant is obliged to ask for this approval and comply with its content.

[21] Cluj Court of Appeal, Section II adm.-tax department, civil sentence no.. 9885 from November 28, 2012.

Moreover, it was stated in this case the fact that the National Health Insurance House was not summoned in the trial as defendant, given that the task for approval of the amounts to be returned belongs to it, as noted previously, and that as long as the legal rules require a certain procedure from the county house, the defendant may not be ordered to directly refund the amounts, moreso because proof was presented that the required documentation had already been submitted to CNAS.

In an adjacent situation, the European court of human rights in Strasbourg[22] was put in a position to analyze the conditions of the settlement from health insurance funds of expenses incurred by a policyholder for the treatment given abroad, in view of the need of prior approval from the competent national authority and the existence of a good, in the sense of art. 1 of the First Protocol to the Convention[23].

In this case, besides the injury on art. 1 of the First Protocol to the Convention the plaintiff also invoked injury regarding his personal right to a fair trial guaranteed by art. 6 of the Convention, considered breached by the European Court of Human Rights on the grounds that neither the plaintiff personally nor the witnesses proposed were heard by the court, to which the excessive length of judicial and administrative proceedings was added.

In fact, it held that the plaintiff suffers from multiple sclerosis and that during 17.05.1994-28.06.21994 has received treatment in the H.H.I. hospital in the U.S. There was a string of domestic lawsuits in the courts of the State of origin, defendant in the case before the European jurisdiction, for reimbursement of medical expenses incurred by the Health Insurance Fund started on 29. 11.1994 and finished with a final decision on 22.01.2009.

As shown[24], the ECHR decision maintains the constant case law of this jurisdiction from the perspective of examining the case under art. 6 of the Convention, but shows interest from the perspective of examining the conditions in which the medical expenses incurred by the plaintiff could be settled.

In this context, the Strasbourg Court held that the interpretation of national legislation by the jurisdiction of the respondent State is within its competence and

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[22] ECHR, judgment of October 15, 2015 in the case Mitkov against the former Yugoslav Republic of Macedonia, request no. 48386/09 available at the website: http://hudoc.echr.coe.int/eng?i=001-157698#{"itemid":["001-157698"]}.

[23] For a brief analysis of this decision see Razvan Anghel, Case Mitkov vs. the former Yugoslav Republic of Macedonia. Terms of the settlement from health insurance funds of expenses incurred for medical treatment in another state. Lack of prior administrative approval. Lack of legitimate expectation within the meaning of art. 1 of Protocol no. 1 to the Convention, at website: http://www.hotararicedo.ro/index.php/news/2015/10/mitkova-c-fosta-republica-iugoslava-a-macedoniei-decontari-fonduri-asigurari-sociale-sanatate-cheltuieli-tratament-medical-in-alt-stat-lipsa-aprobarii-administrative-inexistenta-sperante-legitime-art-1-protocolul-1.

[24] R. Anghel, *op.cit.*, p. 1.

thus it is not being questioned. In this case, the Court noted that nothing can lead to the conclusion that the administrative court has interpret and applied the national law manifestly erroneous or has reached arbitrary conclusions.

As was correctly noted[25], the Court held the interpretation of national courts given in relation to applicable laws, in that the plaintiff had to obtain prior authorization from the competent administrative authority in order to receive treatment abroad. From this perspective, the Court does not examine whether the stage of obtaining prior authorization could be omitted in case of a medical emergency or other circumstances.

In this context, as the author of the comment in this case noted, it is necessary to mention that there were at least two cases[26] in Luxembourg pending before the European Court of Justice (CJUE) with regard to the national legal system and the jurisdiction of the European administrative court in the light of the European Council Regulation (EEC) no. 1408/71 of July 14, 1971, especially art. 22. Obviously, the analysis from the perspective of the ECHR is circumscribed only in the event that such a regulation would be applicable to the plaintiff, which in the present case examined above was not the case, as the former Yugoslav Republic of Macedonia is not an EU member state and therefore that regulation does not apply to it.

By the Order[27] from July 11, 2013 CJUE has established that: *Article 49 EC and Article 22 of the Regulation (EEC) no. 1408/71 of June 14, 1971 on the application of social security schemes to employed persons, to self-employed persons and their families moving within the Community, as amended and updated by Council Regulation (EC) no. 118/97 of December 2, 1996, as amended by Regulation (EC) no. 592/2008 of the European Parliament and of the Council of June 17, 2008 do not oppose the legislation of a Member State which conditions full reimbursement of expenses related to hospital care provided in another Member State to obtaining prior authorization. On the contrary, those articles preclude such legislation interpreted as excluding, in all cases, full reimbursement by the competent institution of the expenses related to such care*

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[25] R. Anghel, *op.cit.*, p. 4.

[26] Case file C-430/12 *Luca*, Ordinance dated July 11, 2013 available at: http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30ddd903729060174ae0baa8b74d417390fe.e34KaxiLc3qMb40Rch0SaxuTbx50?text=&docid=139803&pageIndex=0&doclang=RO&mode=lst&dir=&occ=first&part=1&cid=579118 and case file C-268/13 *Petru*, Decision dated October 9, 2014 available at: http://curia.europa.eu/juris/document/document.jsf?text=&docid=158423&pageIndex=0&doclang=RO&mode=lst&dir=&occ=first&part=1&cid=579535.

[27] CJUE ruled on the order under art. 99 of the Rules of Procedure, retaining the case hypothesis that the answer to a question stated as preliminary may be clearly deduced from the case (para. 15 and 16). In pending cases, the CJEU has had particular regard to previous case law in a similar case that involved examination of EU law from the perspective of the Bulgarian Health Insurance right in the Elchinov case file C-173/09 available at the website: http://curia.europa.eu/juris/document/document.jsf?text=&docid=81396&pageIndex=0&doclang=RO&mode=lst&dir=&occ=first&part=1&cid=586242.

without prior authorization granted. When a refusal of reimbursement, motivated only by the absence of prior authorization, of expenses related to hospital care provided in another Member State and paid by the insured person is not grounded, taking into account the specific circumstances, the cost of care must be reimbursed by the competent institution to the person insured in question, not exceeding the amount determined by the law of that Member State. Where that amount is below that which would result from the application of the legislation in force in the Member State in which the insured person is a resident, in case of hospitalization in this latter State, the competent institution must pay in addition a further refund for the difference between these two values, not exceeding the expense actually incurred. When such a refusal is grounded, the insured person may request, under art. 49 EC, the reimbursement of expenses related to hospital care only in the extent of the amount guaranteed by the health insurance scheme to which he/she is affiliated.

As inferred from the order of the CJEU in fact it was noted that in *October 2008, Mrs. Luca was subjected to medical examinations at the university clinic in Vienna, the cost being 4 822.15 euros. Mrs. Luca subsequently requested, on January 26, 2009, a Form E 112 to perform medical treatment at the same clinic. However, two days later, she asked that the application be adjourned. Following a request for reimbursement of medical expenses for this treatment, formulated on February 12, 2009, the Health Insurance House in Bacau repaid Mrs. Luca 8 123.28 RON. On August 12, 2009, Mrs. Luca made a new application for an E 112 form to carry out the second stage of treatment envisaged at the same clinic. On June 18, 2009 and on October 13, 2009, she also asked for reimbursement of expenses incurred in her treatment. The Health Insurance House in Bacau later decided, on November 12, 2009 to reimburse 4 544.89 RON.*

The Bacau Court later dismissed the application noting that *applications for issuing form E 112 were submitted after the insured person had paid the treatments abroad, so that no fault of the Health Insurance House in Bacau could be considered for the fact that it had not released that form and that it conducted a partial reimbursement of medical expenses incurred. The court pointed out, moreover, that Mrs. Luca did not dispute the calculation of the amounts which were settled under Article 7[1] para. (1) of Order 122/2007 and art. 8 of the Order 729/2009.*

At the appeal against that judgment the Court of Appeal in Bacau asked CJUE to interpret EU law in this case.

In the context of this analysis, CJEU held, *inter alia*, in particular with reference to the earlier case Elchinov C-173/09, that prior authorization by the internal administrative body required by CNAS Order no. 592/2008 is compatible with art. 49 EC of the Regulation no. 1408/71 but that it is necessary that all the conditions attached to this prior authorization be justified in relation to certain

regulations of public interest so that they do not exceed what is necessary to achieve that purpose and that the same result cannot be obtained by more stringent rules and that such a system must be based on objective, non-discriminatory criteria and known in advance, so as to limit the exercise of discretion by the national authorities so that it is not used arbitrarily. CJUE concludes that art. 49 EC and art. 22 of Regulation no. 1408/71 preclude a Member State regulation interpreted as excluding, in all cases, the reimbursement of expenses related to hospital care without prior authorization granted in another Member State.

As regards to the competent institution paying the cost of hospital treatment provided in another Member State, CJEU held that hospital treatment provided in another Member State shall be reimbursed by the competent institution within the amount fixed by the law of that Member State if they have been subject to authorization imposed by art. 22 (1) (c) of Regulation no. 1408/71. If that amount is less than that which would result from the legislation in force in the Member State of residence of the insured person in case of hospitalization in the latter state, should be paid in addition by the competent institution under Article 49 EC, as interpreted by the Court, a further refund the difference between these two values exceeding the expense actually incurred.

CJEU thus concludes that Article 49 EC and Article 22 of Regulation No. 1408/71 does not oppose in principle a national rule which makes the full reimbursement of expenses related to hospital care provided in another Member State to obtain prior authorization, but that instead these articles preclude such legislation if it excludes in all cases, full reimbursement of expenses related to such care without prior authorization granted.

However the European Court stresses, regarding this case, that it may be useful to note that the issue of prior authorization and form E 112 does not appear to present any use when hospital care has already been granted to the insured person, except possibly in the case in which they have not yet been invoiced to the person concerned or have not been paid (Elchinov judgment, paragraph 75). Instead, the reimbursement by the competent institution of expenses related to such care within the amount established by the legislation of the Member State in which it was granted shall be imposed if the denial of reimbursement is motivated only by the absence of prior authorization, taking into account the particular circumstances whose appreciation is for the referring court, considered unfounded.

By judgment of October 9, 2014 handed down by the CJUE in the case file *Petru* C-268/13, it was decided that: *Article 22 (2) second subparagraph of Regulation (EEC) No. 1408/71 of June 14, 1971 on the application of social security schemes to employed persons, to self-employed persons and their families moving within the Community, as amended and updated by Council Regulation (EC) No. 118/97 of December 2, 1996, as amended by Regulation (EC) no. 592/2008 of the European Parliament and of the Council of June 17, 2008, be*

interpreted as meaning that the authorization required under paragraph (1) (c) (i) thereof cannot be refused where the hospital treatment in question cannot be timely given in the Member State of residence of the insured person due to lack of essentials medicines and medical supplies. This impossibility must be assessed at the level of all hospitals in that Member State to grant such treatment and in relation to the timeframe in which the latter can be obtained in a timely manner.

From the judgment it results that… *Mrs. Petru has been suffering from several years of serious vascular disease. In 2007, she suffered a heart attack after which she was subjected to surgery. In 2009, her health worsened and she was admitted to the Institute of Cardiovascular Diseases in Timisoara. Following the medical examinations to which she was subjected it was decided to conduct open heart surgery for mitral valve change and the introduction of two vascular prostheses. Considering that the material conditions in the hospital were not satisfactory to perform such surgery, Mrs. Petru decided to go to a clinic in Germany where the intervention in question was carried out. The cost and postoperative hospitalization expenses amounted to a total of EUR 17 714.70. Before traveling to Germany, Mrs. Petru had asked the County House of Health Insurance Sibiu to bear the costs of intervention on Form E 112. The request was registered on March 2, 2009, and was rejected on the grounds that the contents of the report does not show that the physician requested, who was part of the basic services package, could not be carried out in a reasonable time in health facilities in Romania, based on the current medical condition of the insured person and the evolution of the disease.*

The application for summons introduced on November 2, 2011 in order to recover the sum of 17714.70 EUR and CAS Sibiu and CNAS was rejected and an appeal was made against that decision before the Sibiu Court which decided to make a referral to CJUE to rule on the preliminary procedure provided for in art. 267 TFEU.

After examining art. 22 paragraph 2 of the Rules no. 1408-1471 CJEU held that the text lays down two conditions whose fulfillment makes mandatory the release by the competent institution of the prior authorization required under paragraph (1) (c) (i) thereof. The first condition requires that the treatment be among the benefits provided by the legislation of the Member State in which the insured person resides. The second condition requires that the treatment which the latter plans to receive in another Member State than the state in which he resides, taking into account his current state of health and the probable course of his illness, cannot be granted in the time normally required to obtain treatment in the Member State in which he resides. Regarding the second condition, which is concerned by the preliminary question in the present case, the Court has already held that the requested authorization cannot be refused where identical treatment or having the same degree of effectiveness cannot be obtained in a timely manner

in the Member State of residence of the person concerned. In order assess whether a treatment that presents the same degree of effectiveness can be obtained in a timely manner in the Member State of residence, the Court stated that the competent institution is obliged to consider all the circumstances that characterize each case, taking due account not only of the patient's condition at the time when authorization is sought but also, if necessary, the degree of pain or the nature of his/her disability, which could, for example, make it impossible or excessively difficult to perform a job, and also its history.

In this context, among the circumstances which the competent institution is required to take into consideration may be included, in a particular case, the lack of drugs and medical supplies of basic necessity, such as that alleged in the main proceedings. As the General lawyer showed in point 25 of his Opinion, art. 22 (2) of the Rules no. 1408/71 does not distinguish on the reasons why a certain performance cannot be done in time. This lack of medicines and medical supplies can, as in the case of lack of specific equipment or specialist skills, make it is impossible to grant identical treatment or having the same degree of efficacy in a timely manner in the Member State of residence.

The Court concludes that this impossibility must be assessed, on the one hand, overall, for hospitals in the Member State of residence able to give the specified treatment, and on the other hand, in relation to the timeframe in which the latter can be obtained in a timely manner.

With specific reference to the case, CJEU held that it is for the referring court to assess whether the intervention could have been achieved in time (three months, according to the physician's report quoted in the judgment) in another hospital in Romania, taking into account the defenses of the Romanian government which considers that Mrs. Petru had the right to address any hospital in Romania with the necessary equipment required for the intervention she needed but also the contention invoked by Mrs. Petru on the lack of drugs and materials of first necessity at the Cardiovascular Institute in Timişoara.

4. Instead of conclusions

I presented in the foregoing a synthesis of case law intended to question the complexity of the case law related to both the legal regime *illo tempore* of contributions for health insurance and the right of patients to insurance and healthcare, in particular through the financing of health services.

Regarding the first issue addressed, it was revealed that health insurance contributions were qualified by the legislator as tax receivables with all consequences including regulation in material tax law and management by the tax body of common law, eliminating failures caused by the old point of view.

Moreover, one can notice with just cause that given the complexity of the legal relationship of health insurance it is often difficult to distinguish the

substantive jurisdiction of the courts knowing that currently there is no rule explicitly governing the jurisdiction of health insurance, as there are for social security[28].

In this context, often, administrative courts are called upon to resolve requests for refunds or settlement of costs of hospitalization or those of treatment in the country or abroad, starting only from the fact that the question is to examine the legality of an allegedly unjustified refusal given by a public authority.

However, given the complexity and specificity of case law in the sphere of social relations, grafted on the legal relationship of health insurance, it seems desirable to propose the establishment of jurisdiction - by clear rules, in matters of social health insurance – either explicitly through the competence of the administrative courts, either in the jurisdiction of other courts. Only then can we generate a specialization of judges, needed in this complex area, and then of course we can ensure a uniform judicial practice, so necessary in the Romanian judiciary system.

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[28] We have in mind, to file, the legal provisions from Chapter VIII - *Jurisdiction of social insurance* - from Law no. 263/2010 on the unitary system of public pensions, especially art. 152 of the law that stated with great force: *Jurisdiction of social security is achieved by tribunals and courts of appeal.*

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