

Legislative contributions to improving the economic efficiency of the medical laboratories in Romania

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Abstract. *Improving economic activity in a business depends on the legislative framework. Thus, we have conducted a study that aimed to correlate the legislative changes with the economic activity of the medical laboratories in Romania. This article highlights through the conducted research the legislative contributions to the improvement of the economic activity in Romanian medical laboratories. I conclude that the legislative changes in the period 2010-2015 had a positive impact on the economic activity of medical laboratories in Romania and the quality of their activities.*

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JEL Classification: K00.

Introduction

There are three main types of health systems based on the sources of funding:

- social health insurance system, called also the Bismarckian system introduced in Germany in the late 19th century, based on compulsory insurance premiums dependent on income and not the health of the insured;
- National Health System, called also the Beveridge model, named after the man who introduced in England after the Second World War, financed through taxes;
- the voluntary insurance services met if private health insurance premiums is correlated with the risk insured.

The health system in Romania is a Bismarck type of health system, the source of fundings is ensured through the compulsory contribution insurance for health; social health insurance is required from both the employer and the employee.

The health systems offers medical services.

Medical services are services provided by organizations operating in the health sector: hospitals, doctors, public and private medical centres that can be classified according to the services rendered:

- Laboratory medicine services - provided by medical laboratories;
- Occupational health services - provided by occupational medicine clinics;
- Emergency medical services - provided by emergency units;
- General medical services - provided by medical doctors' offices;
- Specialized medical services - provided by specialized medical doctors' offices.

Medical services offered to customers, including the services of medical laboratories depend on the manner of their funding.

The main sources of raising funds for healthcare are:

- Mandatory insurance premium for the entire population, regardless of the health of those who pay;
- General taxes that are collected from by the state and then distributed to the health sector under the budget approved by the competent body such as the Parliament in Romania;
- Voluntary insurance premiums, which are correlated with the health of insured persons;
- Direct payment of health services by the population in their use and co-payment.

The health services of the country cannot be financed exclusively through one mechanism and therefore different forms of funding can co-exist at the same time:

- Government funding based on taxes collected;
- Social health insurance;
- Private health insurance;
- Direct payment of the medical services by customers and co-payments.

Laboratory medicine services - provided by the medical laboratories are an important part of laboratory services whose legal framework for the operation and organization is defined by the Minister of Health No. 119/2004 replaced by the Minister of Health

1301/2007 Rules on operation medical analysis laboratories, stipulating at art. 2 that "medical analysis laboratory is the unit belonging to public and private system, with or without legal personality, which provides medical laboratory services.

Medical laboratory services consist of:

- a) Analysis of materials from the human body through various methods and techniques of biochemistry, hematology, immunochemistry, immunology, microbiology, genetics, cytology, pathology, toxicology, molecular and cellular biology, biophysics, etc., in order to provide information for diagnosis, treatment and prevention of disease or for assessing the health of the population;
- b) Advice on the interpretation of the results of any investigations carried out and for further investigation if necessary."

The end result of medical laboratories is the medical analysis reports containing the patient's medical test results.

The quality of the results (values) of medical tests performed by medical laboratories are influenced by several factors:

- Specialists (number, training and professional experience, their motivation, etc.)
- Facilities, equipment, environment, number of tests performed per hour, automatic or semiautomatic type of machine, measurement methods - examination;
- Reagents, consumables;
- Internal quality control that checks how the device, professionals, reagents and quality working environment are working;
- External quality control that checks the statistical comparability of results regardless of device patients, specialists, quality reagents and working environment;
- The legislative framework for the organization, operation and financing of medical laboratories;
- Laboratory management.

Medical Laboratories contracting analysis reimbursed by the National House of Health Insurance (CNAS) from the health insurance budget must perform a minimum of four annual rounds in external quality control to receive a minimum score and enter the contractual relationship with the National House of Health Insurance – in order to fulfil the quality criteria of the law – Annex. 19, Chapter II, lit. B, Section 2, quality criterion, letter b). – Detailed implementation rules for applying the Contract – Framework for medical assistance in the social health insurance system.

Official documents that refer directly to external quality control which that are also called proficiency testing scheme providers are:

- ISO Standard 17043: 2010 General Requirements for Conformity Assessment proficiency tests;
- Minister of Health no. 2071 from 2007 regarding the notification by the Ministry of Health of the providers of proficiency testing schemes;
- Specific Rules of accreditation for providers of proficiency testing standard 17043: 2010;

and other important references exists in the ISO 15189: 2013 standard for Medical Laboratories regarding the Requirements for quality and competence, the Minister of Health's order number 1301 from 2007 Norms on the Functioning of medical analysis laboratories and rules for the application of the Contract - Framework medical assistance in social health insurance system.

The national legislation with direct impact on the funding of medical laboratories analysed in this study consists of the annually Orders joint approved by the Minister of Health and the President of the Romanian National House of National Health Insurance that implements rules as an Appendix – to the Frame contract for healthcare within the system health insurance.

From the comparative analysis of the stipulations of the Methodological Norms for the period 2010-2015 Contract – Framework regarding the conditions of providing medical assistance in social health insurance system for medical laboratories we observed that from the criteria for selecting healthcare providers of medical analysis the financial terms were eliminated which had a share of 10% in 2010, 5% in 2011 and 2012 and since 2013 has been eliminated as an evaluation and score criteria for medical laboratories in contract with CNAS, the 5% previously granted to the Financial criteria being distributed to the Resource evaluation criteria.

We analyzed the legislative changes of the Methodological Norms for the period 2010-2015 regarding the assessment of technical capacity of the resources and the evaluation of human resource assessment:

- a) increasing of the score for automatic analyzers compared to the semi-automatic considering both speed - the number of tests per hour, the number of parameters and technique used, being better scored modern analytical techniques for devices from all three compartments in the study: Biochemistry, Hematology and Hemostasis;
- b) increase of the score for human resources.

To study the impact of legislative changes regarding the increase of the scores granted by CNAS to contracting analysis with medical laboratories for equipment and human resources over the economic activity of medical laboratories we used information of 84 national medical laboratories from Bucharest and 28 counties participating during 2010 - 2015 on external quality control organized by a national supplier.

Maintaining the confidentiality for the surveyed medical laboratories is ensured by allocating a number from 1-84 to each medical laboratory.

Specialists in medical laboratories

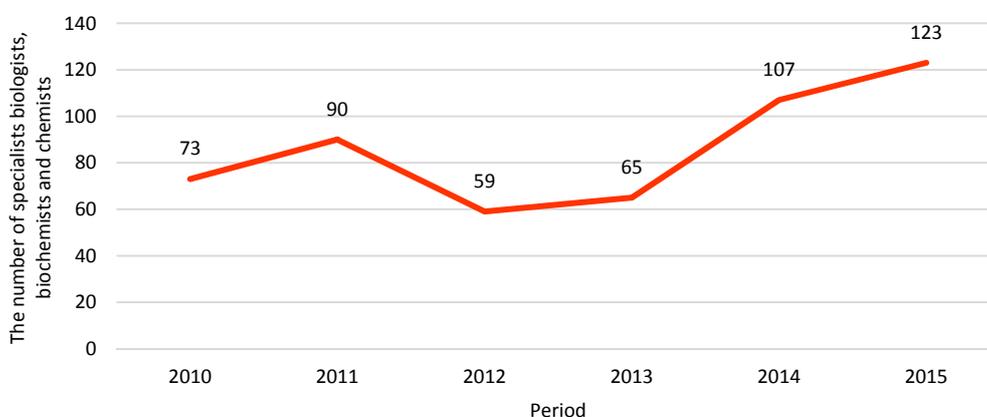
Each medical laboratory that wants to enter into a contractual relationship and to obtain money from CNAS must have a doctor specialized in laboratory medicine hired according to Co-Ca Norms, so every medical laboratory participating in this study has at least one doctor specialized in laboratory medicine hired and that is why we studied in this paper only the number of specialists employed as authorized biologists, chemists, biochemists and that are in the records of the professional organization.

Data analysis shows that the number of specialists employed in medical laboratories in 2015 is:

- Almost 2 times higher than in the private sector in 2013 (Figure 1)
- Over 4 times higher than in the public system in 2013 (Figure 2)

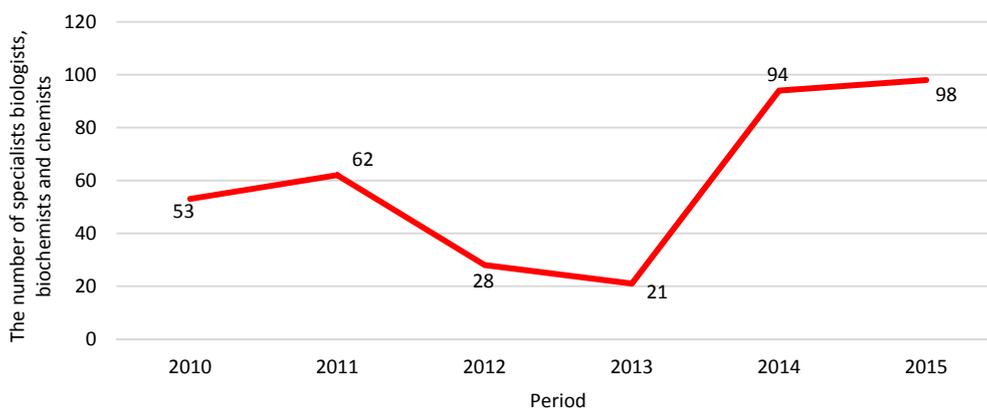
by increasing the score for the main specialists from 16 to 25 points, for those with a medical speciality from 14 to 20 points and for those without a medical speciality from 10 to 15 points.

Figure 1. Evolutions of the number of specialists hired between 2010 and 2015 in the private medical laboratories participating in the study



Source: according to the research.

Figure 2. Evolutions of the number of specialists hired between 2010 and 2015 in the public medical laboratories participating in the study



Source: according to the research.

Equipment

Medical analysis laboratories activity cannot take place without equipment, reagents, calibrators, supplies, etc.

In this paper we analyzed the equipping of the 84 medical laboratories studied during 2010 - 2015 for each department of biochemistry, hematology, hemostasis, the evolution of CNAS score for types of equipment in the fields of biochemistry, hematology, hemostasis and the number of equipments/year that are in their use during 2010-2015 .

The equipment identified are those specified by medical laboratories as participants in external quality control.

For equipment - medical devices of laboratories participating in the study we didn't found an increase in numbers, the predominance of a particular type or model probably due to numerous factors influencing the purchase of some equipment – their cost of reagents, consumables, internal control and but also score granting criteria from CNAS to contracting medical tests when taking into account the age of the equipment, their type – automatic or semi-automatic, the number of tests per hour, methods, etc. but there are certainly also commercial factors influencing the purchase of equipment.

The funds allocated to medical laboratories from the health insurance budget

Funds from the health insurance budget are allocated to medical laboratories according to criteria for selecting healthcare providers of medical laboratory services by adding the amounts determined as follows:

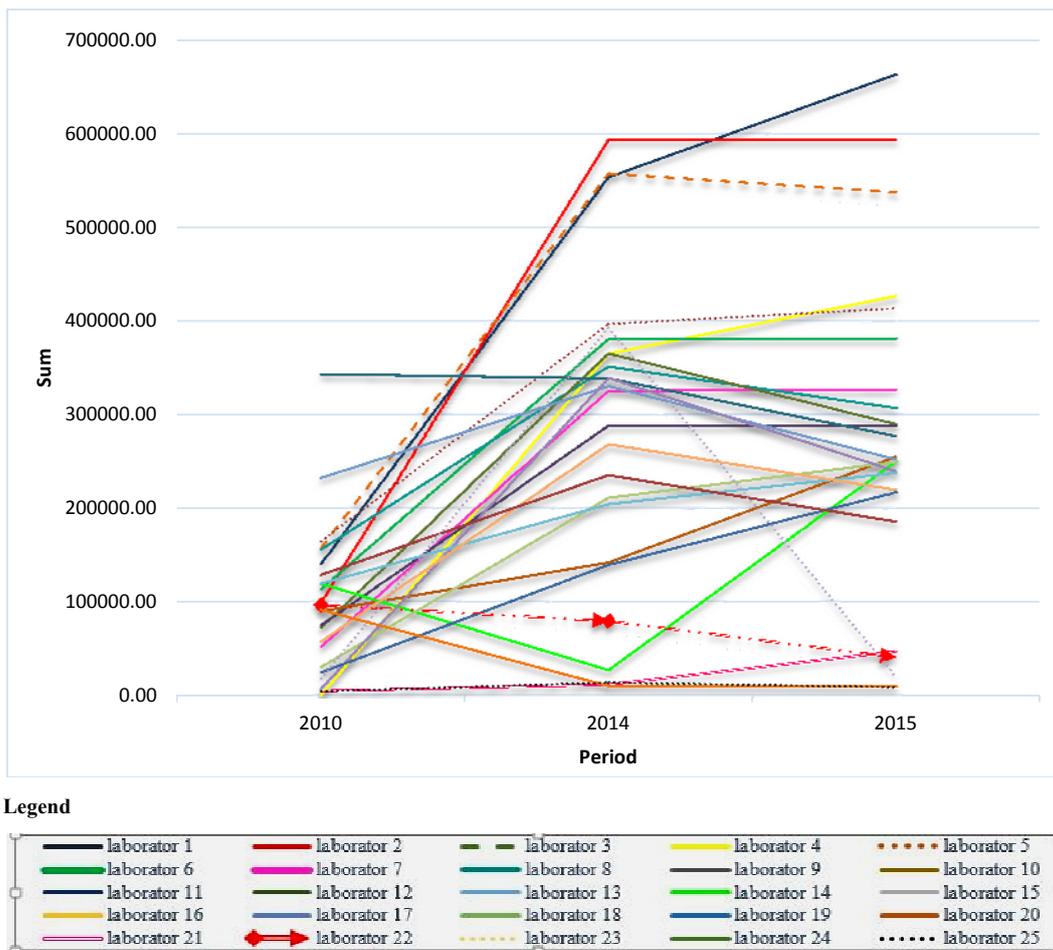
- Adding the number of points obtained by each supplier for each criteria/ sub criteria and thus establishes the total number of points obtained;
- The value of a point for each criteria/sub criteria is calculated by dividing the sum resulted as a result of applying percentage at the number of points suitable to each criteria/sub criteria;
- the value of a point obtained for each criteria/sub criteria is multiplied by the number of points obtained by a supplier suitable to each criteria/sub criteria, resulting the sums for each criteria/sub criteria for each supplier.

For the 84 medical laboratories studied during 2010-2015 we followed the websites of Regional Counties Health Insurance Houses and the Health Insurance House of Bucharest the funds allocated from the budget of the National Health Insurance keeping confidentiality of medical laboratories surveyed by allocating a number to each medical laboratory.

We found complete data on the funds allocated from the budget of the National Health Insurance for 25 of the 84 medical laboratories surveyed for the years 2010, 2014, 2015.

From the data analysis we observed an increase in funds allocated from the budget of the National Health Insurance House for 23 medical laboratories only two with a decrease of allocations by CNAS (Figure 3).

Figure 3. Situation of funds allocated by the National Health Insurance medical laboratories participating in the study for 2010, 2014, 2015



Source: according to research performed.

In Table 1 we present the comparative tariff situation in RON per medical analysis in the fields of biochemistry, hematology and haemostasis as CO-CA Norms for the years 2010 to 2015 settled to medical laboratories by the National Health Insurance in the period 2010-2015.

We can point out that the prices were the same for all analyses and studied parameters during 2010-2015, with a slight increase in 2014 and maintaining the same value in 2015 with the exception of Quick Time analysis of which price increased.

Table 1. Comparison of tariffs lei to medical tests according to Contract Regulations – Framework for the years 2010-2015

Biochemistry

No.	Name of analysis	Code	Tariff 2010 (lei)	Tariff 2011 (lei)	Tariff 2012 (lei)	Tariff 2013 (lei)	Tariff 2014 (lei)	Tariff 2015 (lei)	Code of analysis in 2014
1	Serum urea	21120	5.46	5.46	5.46	5.46	5.86	5.86	21011
2	Serum uric acid	21130	5.46	5.46	5.46	5.46	5.86	5.86	21012
3	Serum creatinine	21140	5.52	5.52	5.52	5.52	5.92	5.92	21014
4	Magnezemia	21570	5	5	5	5	5.37	5.37	210505
5	Sideremia	28390	6.62	6.62	6.62	6.62	7.1	7.1	210506
6	Glucose	21310	5.35	5.35	5.35	5.35	5.74	5.74	21020
7	Total serum cholesterol	21420	5.35	5.35	5.35	5.35	5.74	5.74	210303
8	TGO	24600	5.43	5.43	5.43	5.43	5.83	5.83	210403

Hematology

No.	Name of analysis	Code	Tariff 2010 (lei)	Tariff 2011 (lei)	Tariff 2012 (lei)	Tariff 2013 (lei)	Tariff 2014 (lei)	Tariff 2015 (lei)	Code of analysis in 2014
1	HLG full - Hb, Ht, no. erythrocytes, no. white blood cells, no. platelets, FL, red cell indices	28070	10.27	13.06	13.06	13.06	14.01	14.01	26001

Haemostasia

No.	Name of analysis	Code	Tariff 2010 (lei)	Tariff 2011 (lei)	Tariff 2012 (lei)	Tariff 2013 (lei)	Tariff 2014 (lei)	Tariff 2015 (lei)	Code of analysis in 2014
1	Quick Time active. prothrombin	28621	6.73	6.73	6.73	6.73	10.7	14.68	26101
2	Fibrinogenemie	23210	12.75	12.75	12.75	12.75	13.68	13.68	26103

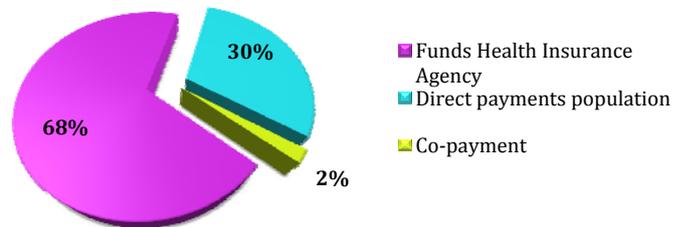
Source: according to research performed by accessing www.cnas.ro

The direct impact of the legislation on the medical laboratories in Romania

In 2012 we distributed the questionnaire to evaluate "the impact of the legislative amendments on the funding of medical laboratories" to a number of 130 medical laboratories in Romania and received completed questionnaires with 52 responses.

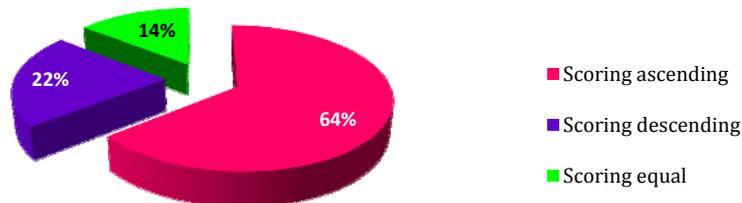
Centralization of the replies to 9 out of the 10 questions in the questionnaire (because the last question of the questionnaire was related to proposals for improving the existing legislation and participants' responses were not included in this study) revealed the following:

- 1) 68% of respondents answered to question 1 that laboratory funding consists for more than 50% of direct payments from the population while 30% reported that that laboratory funding consists for more than 50% of consists of funds from the National Health Insurance House (CNAS) – Figure 4;

Figure 4. *Financing of medical laboratory*

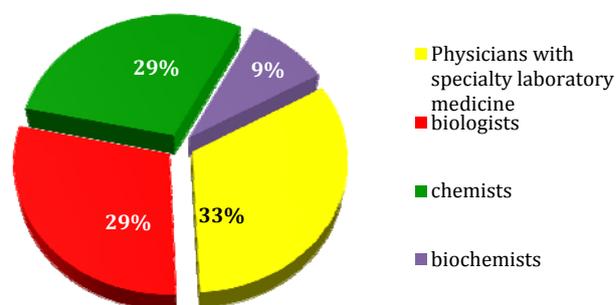
Source: according to the performed research.

2) The score obtained by the medical laboratory from the National Health Insurance House (CNAS) in the period 2010 to 2012 for the laboratories studied was as follows: an increase of the score for 64% of medical laboratories, decrease for 22% of the laboratories and the same score for 14% of the participating medical laboratories study – Figure 5.

Figure 5. *The score obtained by medical laboratories from the National Health Insurance in the period 2010-2012*

Source: according to the performed research.

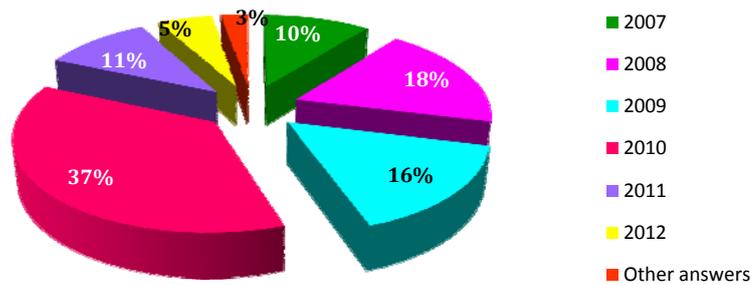
3) The employees in the medical laboratories: 33% are doctors specialized in medical laboratory, 29% biologists, 29% chemists and 9% biochemists according to the answers at question no. 3 of the questionnaire (Figure 6).

Figure 6. *Specialists employed in medical laboratories*

Source: according to the performed research.

4) Most of the respondent laboratories, 37%, said they have implemented a quality management system according to EN ISO 15189: 2007 in 2010 (Figure 7).

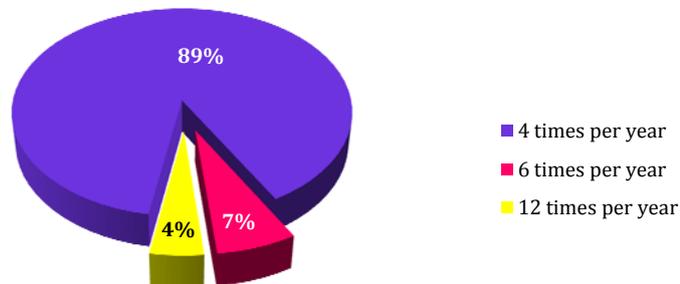
Figure 7. The year declared by participants in the study for the implementation of quality management system according to ISO standard 15189: 2007



Source: according to the performed research.

5) 89% of the medical laboratories surveyed said they participate in proficiency testing schemes (external quality control) 4 times a year, 7% participating 6 times a year and 5% participating 12 times a year – Figure 8;

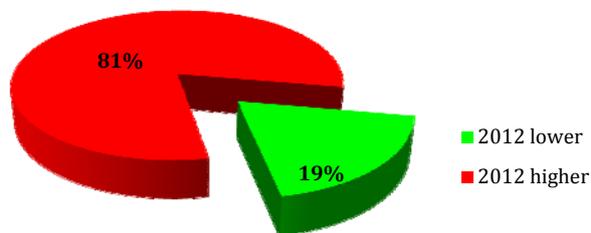
Figure 8. Frequency of participation in external quality control of medical laboratories questioned



Source: according to the performed research.

6) 81% of the medical laboratories said that the score from CNAS in 2012 was higher compared to 2011 (Figure 9).

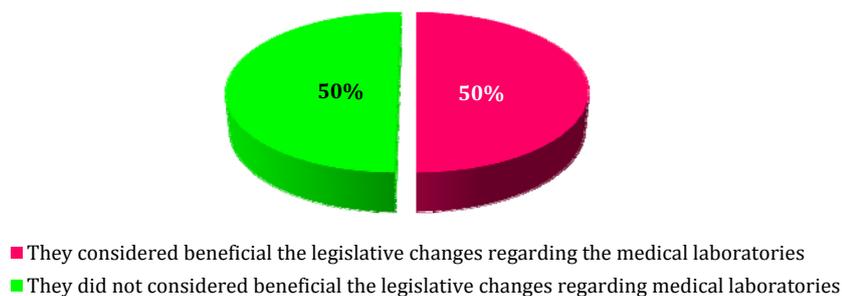
Figure 9. The score obtained by medical laboratories questioned in 2012 compared to 2011



Source: according to the performed research.

7) 50% of the medical laboratories surveyed said they considered beneficial legislative changes related to medical laboratories in the period 2008-2012 and the same percentage 50% is not considered beneficial laboratory (Figure 10).

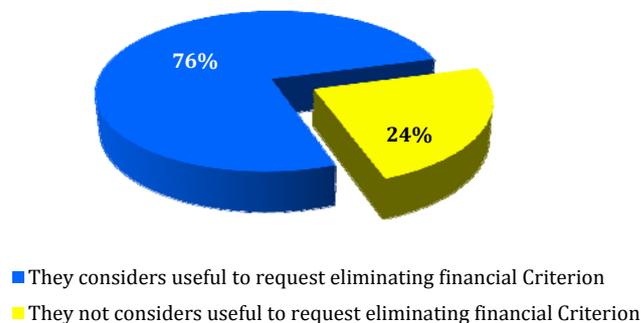
Figure 10. The usefulness of legislative changes regarding the medical laboratories between 2008 and 2012



Source: according to the performed research.

8) 76% of the medical laboratories consider relevant the request for eliminating the financial Criterion (point 3 A, Chapter II of the Rules on the Framework Agreement for 2013 (Figure 11).

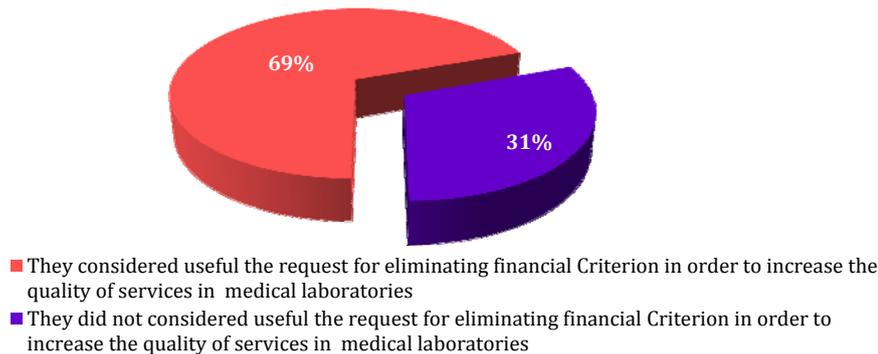
Figure 11. The usefulness of the request to eliminate financial criterion



Source: according to research performed.

- 9) 69% of the surveyed medical laboratories consider that abolishing the financial Criterion rules in the 2013 Framework Agreement would help to increase service quality in the medical laboratories (Figure 12).

Figure 12. *The usefulness of the request to eliminate financial Criterion to increase the quality of medical services*



Source: according to research performed.

Conclusion

The study conducted between 2010 and 2015 on legislative changes on the economic activity of medical laboratories has revealed the following:

1. The financing of the medical analysis laboratories in the period 2012-2013 still comes for more than 50% from direct payments of the population, according to the responses to questionnaires (68% of respondents) although the funds allocated from the budget of the National Health Insurance increased throughout the period 2010-2015.
2. The funds allocated from the budget of the National Health Insurance (CNAS) increased steadily during the period 2010-2015 for 23 of the 25 medical laboratories studied, only two medical laboratories reported a decrease of allocations by the National Health Insurance in 2010, 2014, 2015.
3. 50% of medical laboratories surveyed said that legislative changes regulating the medical laboratories in the period 2008-2012 were beneficial and the same percentage 50% have not considered them beneficial to their activities.
4. 76% of the medical laboratories found useful the removal of the financial Criterion in 2012 from the Framework contract and 69% of the medical laboratories considered that eliminating the financial Criterion rules in the 2013 Framework Agreement would help to increase service quality medical laboratories.
5. The financial criterion has been removed by the National Health Insurance from 2013 as an evaluation criteria and the score granted before for the medical laboratories, the 5% previously granted for the financial criteria in 2011 and 2012 was distributed for the criteria of resource evaluation.

6. The increase of the medical laboratories funds allocated from the budget of the National Health Insurance was realized by increasing the laboratories scores awarded for the performance assessment criteria.
7. In the period from 2010 to 2015 we observed an increase in the number of specialists employed in medical laboratories; in 2015 their number is:
 - Almost 2 times higher than for the private laboratories in 2013.
 - Over 4 times higher than in 2013 for the public laboratories.
8. The increase of the number of specialists employed by the medical laboratories in the period 2010-2015 is in close correlation with increased scores awarded for Principal professionals (biologists, chemists, biochemists) from 16 to 25 points, for those with a Medical Speciality from 14 to 20 points and for those without a medical specialty from 10 to 15 points over the same period from 2010 to 2015.
9. We found no correlation between equipping - acquisition of devices and the medical laboratories score awarded by the National Health Insurance Fund for the period 2010-2015.
10. Prices in lei per medical analysis in the fields of Biochemistry, Hematology and Haemostasis under Contract Regulations - Framework for the years 2010-2015 were the same for all analyses and studied parameters during 2010-2015, with a slight increase in 2014 and a stagnation in 2015 except Quick Time analysis whose price rose.

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