EMERGENCY ORDINANCE No. 93 of 24 June 2008

on amendment of Law No. 95/2006 on healthcare reform

Having in view the necessity of accelerated healthcare system reform process to provide citizens with quality medical services, taking into consideration elimination of certain malfunctions in practice through enforcement of Law No. 95/2006 on healthcare reform, as amended, taking into account the necessary establishment of a legal framework, in view of the institutional reorganisation of the Ministry of Public Health, in view of efficient management of human and financial resources in the field of public health, and in order to closely and thoroughly understand the actual healthcare needs of population in communities, taking into consideration the urgent need for set up of the legal framework for application of Regulation (EC) No. 1.901/2006 of the European Parliament and of the Council concerning medicinal products for paediatric use, as amended, and of Regulation (EC) No. 1.394/2007 of the European Parliament and of the Council concerning advanced therapy medicinal products, amending Directive 2001/83/EC on the set up of a community code, having in mind that the Ministry of Transportation own healthcare network is the only healthcare network where doctor managers may not carry out medical activities in hospitals under 400 beds, it is our appreciation that lack of adoption of this emergency ordinance would lead to serious malfunctions in development of national healthcare programs, in ensuring qualified personnel in disadvantaged areas, in administration and functioning of healthcare units in the Ministry of Transportation own network, which are spread out over several administrative districts of the country, making a national network of all means of transport (railway, road, air, naval), of particular specificity in relation to strategic insurance of traveller and goods safety transportation at the national level, a fact which could affect the effectiveness of specific control activity for persons in charge with the safety of circulation and navigation etc.

Based on Article 115 (4) of the Constitution of Romania, republished,

The Romanian Government hereby adopts the following emergency ordinance:

Article I – Law No. 95/2006 on healthcare reform, published in the Official gazette of Romania, Part I, No. 372 of 28 April 2006, as amended, shall be amended as follows:

1. Article 4 (1), e) shall be amended as follows:

"e) public healthcare control – enforcement of control activities on enforcement of legal provisions concerning public healthcare".

2. Article 8, b) shall be amended as follows:

"b) Public healthcare control;".

3. Article 11 shall be amended as follows:

"Article 11. – In view of this law, "public healthcare authorities" shall mean:

a) The Minister of Public Health, a specialised legal entity of the central public administration, subordinated to the Government;

b) other institutions carrying out activities in the public healthcare field on national, regional, county or local level."

4. Article 15 shall be amended as follows:

"Article 15. – The legal entities carrying out activities in the field of public healthcare on national, regional, county or local level, subordinated or under the coordination of the Ministry of Public Health, are set up, reorganised and revoked by Government Decision."

5. Article 16 shall be amended as follows:

"Article 16. – (1) The Minister of Public Health, as central authority in the field of public health assistance, mainly has the following attributions and responsibilities:

a) establishing the national public healthcare priorities, issues and implements the national healthcare programs financed by the state budget and by personal revenues of the Ministry of Public Health, as well as from the budget of the single national health insurance fund, via the subordinated institutions;

b) issuing and approving regulations in the healthcare field;

c) periodically assessing public health indicators, national healthcare programs indicators, as well as the performance indicators of public hospital management and submitting periodic reports to the Government;

d) ensuring public healthcare control;

e) coordinating, implementing and monitoring of community financed projects as well as other bilateral agreements, the healthcare stability pact and other international agreements in its area of competence;

f) scientifically and methodologically coordinating the medical care network via the special commissions of the Ministry of Public Health.

(2) Members of the special commission mentioned under (1) f) receive a monthly allowance of 10% of the Secretary of State's allowance, granted in direct proportion with the number of the number of actual participations in meetings.

Occasional travel expenses for participation in special committees are reimbursed by the public institutions where the respective persons belong or carry out their clinical integration activities. Expenses concerning travel to other cities, occurred due to participation in the special committee on family medicine, are reimbursed by the Ministry of Public Health. The organisation and functioning regulation and the attributions of the special committees are established through a Minister of Public Health Order."

6. The name of Chapter IV "Health state inspection" of title I "Public Healthcare" shall be amended as follows:

"CHAPTER IV
Public Healthcare Control"

7. Throughout the law content, the phrase "national healthcare inspection" is replaced by "public healthcare control".

8. Article 25 shall be amended as follows:

"Article 25. – (1) Public healthcare control is organised according to specific domains, coordinated by institutions with attributions in the field of control on national and regional level, according to competence.

(2) Public healthcare control is conducted in the following areas:

a) quality of healthcare services;

b) public healthcare;

c) pharmaceutical;

d) medical devices."

9. Article 26 shall be amended as follows:

"Article 26. – (1) Public healthcare control is undertaken by the specialised staff of institutions with responsibilities in public healthcare control, according to the general and specific norms they issue and approved through Minister of Public Health Order.

(2) In order to carry out a public healthcare control, the assigned staff has the right to:

a) access any type of units, documents, information, according to competence;

b) collect products potentially hazardous for public health;

c) find and sanction contraventions under public healthcare legislation.

(3) Under public health hazardous circumstances, authorised personnel may forbid the marketing of products, may decide upon their withdrawal, temporary or permanent suspension of activities, withdrawal or cancellation of the sanitary functioning authorisation, of healthcare compliance letter, of notifications for activities and products and may order any other measures circumstances may require.

(4) In cases of epidemiological hazard, the authorised personnel may impose particular measures for patients, suspects and contacts of transmissible diseases or carriers of pathogenic germs, as well as other measures in order to limit the movement of persons.

(5) The conclusions of control activities, deviations from legal norms, recommendations and deadlines for remedy of deficiencies, as well as other legal measures applied shall be recorded in minutes for assessment of hygienic-sanitary conditions, inspection reports and contravention finding records, if appropriate.

(6) When carrying out the activity, authorised personnel ensures maintenance of the data confidentiality, except for situations representing a public health risk, in which case the communication shall be done through the legal representative."

10. Article 45 (1) and (2) shall be amended as follows:

"Article 45. – (1) National healthcare programs represent a set of multi-annual actions, organised in view of assessment, prevention, treatment and control of diseases with major impact on the health of the population.

(2) The Ministry of Public Health ensures the elaboration and coordination of national healthcare programs, in accordance with national healthcare policies and strategies, as well as the financing of healthcare programs."

11. Under Article 48, paragraphs (1^1) and (1^2) shall be amended as follows:

"(1^1) The Ministry of Economy and Finances is hereby authorised to introduce, at the proposal of the main credit ordinators, the corresponding modifications in the structure of the state budget, the Ministry of Public Health budget and of the budget resulted from entirely own revenue financed activities, attached hereby, and in the volume and structure of the single national health insurance fund, approved for 2008, without affecting the state budget deficit and the consolidated budget deficit for 2008.

(1^2) The main credit ordinators are authorised to introduce the corresponding modifications into the annexes to the Ministry of Public Health budget and the budget of the Single National Health Insurance Fund approved for 2008."

12. Under Article 48, two new paragraphs shall be added after (4), paragraphs (5) and (6), as follows:

"(5) Medicinal products, sanitary materials, medical devices and such, dispensed via closed-circuit pharmacies, which are granted to both patients and patients included in national healthcare programs assigned through Government decision shall be covered at reimbursement price level.

(6) Medicinal products, sanitary materials, medical devices and such, employed in the healthcare bed containing units, during hospitalisation for patient specific treatment as well as for patients included in national healthcare programs assigned through Government decision shall be acquired at a price not exceeding the settlement price approved through Minister of Public Health Order, in accordance with the Law."

13. Article 49 shall be amended as follows:

"Article 49. – (1) National healthcare programs shall be carried out through specialised units, selected based on criteria approved through Minister of Public Health Order, at the proposal of the NHIH (the National Health Insurance House) for healthcare, medicinal products and medical devices providers under contract with the NHIH and on opinion endorsement of Minister of Public Health specialised committees for other institutions and organisations.

(2) In accordance with this law, specialised units are as follows: authorised and evaluated public and private healthcare units, public institutions, medical service, medicinal products and medical devices providers, under contract with the health insurance units, as well as other governmental and non-governmental institutions and organisations. For the purpose of this law, the specialised units are:

(3) Specialised units mentioned in (2) may employ staff to undertake national healthcare programs as multi-annual activities throughout the entire period of their enforcement"

14. Under Article 50, d) is hereby amended and shall read as follows:

"d) proposes national healthcare programs for Government approval."

15. Under Article 54, (1) is hereby amended and shall read as follows:

"Article 54. – (1) Financing of national healthcare programs is undertaken based on the state budget, from Ministry of Public Health incomes, the budget of the Single national health insurance fund, transfers from the state budget and own revenues, via the Ministry of Public Health budget to the budget of the single national health insurance fund, as well as

from other sources, including donations and funding from sponsorships, in accordance with the law."

16. Under Article 54, (1^1) is repealed.

17. Under Article 60, d) and f) are amended and shall read as follows:

"d) general practitioner – a medical diploma holder, awarded prior to 2005, who has not attended specialist training and has been granted the free practice right based on the provisions prior to this law;

.....

f) family medicine cabinet – private healthcare unit specialised in providing primary healthcare services, set up in accordance with the law. By way of exception, ministries and institutions provided with their own healthcare network may establish family medicine cabinets as public healthcare units."

18. Under Article 60, a new point is introduced after l), m), which reads as follows:

"m) practitioner, holder of a family medicine cabinet – physician holding the asset of professional patrimony of affectation or part thereof."

19. Article 69 is hereby amended and shall read as follows:

"Article 69. – (1) The set up of a new family medicine cabinet in a locality is established in accordance with the legal provisions. The methodology is established by norms approved through Minister of Public Health Order.

(2) Contracting and decontracting family medicine services carried out by the county health insurance houses, the Bucharest health insurance house, the Health Insurance House of the Ministry of Defence, Public Order, National Security and Judicial Authority, as well as the Health Insurance House of the Ministry of Transportation, Constructions and Tourism before reorganisation is performed for physicians mentioned under Article 60 d), under contract as of 1 January 2007, as well as for specialised family doctors. These provisions also apply to specialised family doctors, holders of a general practitioner certificate released by a member state, for whom provisions of Article 388 - 390 apply or who are in the situation laid down in Article 397.

(3) Restarting an activity of an existing practice by a different family doctor, in terms of the end of the holder’s activity, is performed through transmission of the capital of professional affectation held by the practitioner who undertakes the practice retrieval. The new holder shall inform the territorial public health authorities, the healthcare units, and the patients as well, about the practice retrieval. The criteria and retrieval methodology are

established through norms approved through Minister of Public Health Order."

20. A new article is introduced after Article 69, Article 69^1, as follows:

"Article 69^1. – (1) Local public administration authorities can provide facilities and incentives relating to the settling of a physician, the settling and functioning of a family medicine cabinet, in accordance with legal provisions.

(2) Based on provisions under (1), local public administration authorities together with the legal representative of the family medicine cabinet may sign a civil contract in partnership with the legal representative of the family medicine cabinet specifying the rights and duties of parties involved."

21. A new article is introduced after Article 81, Article 81^1, which reads as follows:

"Article 81^1. – (1) In rural settings, expenses may be financed from the state budget, via the Minister of Public Health budget, for infrastructure investments, in view of construction, rehabilitation, standard minimum endowment of medical and non-medical premises where primary healthcare activities are carried out, as well as in view of carrying out other national healthcare programs.

(2) The Ministry of Public Health shall allocate the sums mentioned under (1) as transfers from county public health authorities to local public administration authorities"

22. Under Article 86, a new paragraph is introduced after (2), paragraph (3), which reads as follows:

"(3) The positions of emergency admission unit chief physician, chief physician of the MESRE (Mobile Emergency Service for Resuscitation and Extrication) emergency admission unit – or Emergency Admission Unit (EAU) chief physician may be held by physicians with a minimum of 5 years experience in this field. By way of exception, as of 2008 – 2010, these positions may also be held by physicians with minimum 3 years experience in the field."

23. Under Article 93, a new paragraph is introduced after (1), paragraph (1^1), which reads as follows:

"(1^1) From the Ministry of Public Health budget and the funds allocated from state budget and own revenues, expenses for medicinal products and healthcare materials as well as expenses for insurance of the given operational intervention means are ensured for the public ambulance services.

24. Under Article 93, paragraph (5) is amended and shall read as follows:

"(5) Units and emergency admission compartments within hospitals with emergency structures approved in accordance with legal provisions are financed from the state budget as well as from Ministry of Public Health venues, containing staff expenses amounts, expenses incurred by medicinal products, reagents and healthcare materials, paraclinical investigation expenses for cases solved within these structures, which do not require hospitalisation in the unit where the respective emergency admission unit chief physician or EAU chief physician belongs, as well as amounts due for other products and services meant for maintenance and functioning of these structures."

25. Two additional paragraphs, (5^1) and (5^2), are introduced under Article 93, after paragraph (5), which shall read as follows:

"(5^1) For emergency admission units implying a MESRE, apart from amounts under Article (5) from the state budget and Ministry of Public Health individual incomes, sums shall also be allocated for such expenses as:

a) expenses for staff of the emergency admission unit participating in MESRE interventions;

b) expenses for medicinal products and healthcare materials for mobile intensive therapy teams and qualified first aid teams;

c) expenses for given transmissions for mobile intensive therapy teams and for qualified first aid teams;

d) maintenance and verification expenses for medical equipment for mobile intensive therapy teams and qualified first aid teams;

e) expenses for insurance of necessary intervention means for mobile intensive therapy teams and qualified first aid teams;

f) expenses for the functioning and maintenance of qualified first aid teams intervention means operating in the MESRE system, within the structure of the non-profit public services for emergency situations, except for paramedical personnel expenses meant for these teams. Such expenses may also be co-financed from the local budget, based on certain cooperation protocols signed between the hospital including the emergency admission unit coordinating the medical activity within the MESRE, the town hall or the involved county council and the Inspectorate for Emergency Situations in the respective county or in Bucharest;

g) expenses for medicinal products and healthcare materials, as well as for maintenance expenses and verification expenses for medical

equipment of intervention special vehicle(s) in case of collective accidents or disasters, as required;

h) expenses for functioning and maintenance of the intervention special vehicle(s) used within the MESRE medical intervention regional coordinating structure, in case they exist.

(5^2) Details of expenses under (5^1) and reimbursement means are established through norms approved through joint order of the Minister of Public Health and the Minister of the Interior and Administrative Reform."

26. Under Article 136, (2) is hereby amended and shall read as follows:

"(2) Professional categories mentioned under (1) b) and d) are employed based on individual labour contracts, as a multi-annual task, at the named healthcare units, and staff expenses shall be paid within national healthcare programs."

27. Under Article 174, (3^1) is hereby amended and shall read as follows:

"(3^1) The organisational structure of public healthcare bed containing units subordinated to the Ministry of Public Health is approved through Minister of Public Health Order, at the manager's proposal or Minister of Public Health initiative, in accordance with legal provisions in force."

28. Under Article 174, a new paragraph is introduced after (3^1), paragraph (3^2), which reads as follows:

"(3^2) The organisational structure, reorganisation, change of site and names of healthcare units under ministries and units provided with their own sanitary network shall be established through minister order, decision of the institution manager, authorised by the Ministry of Public Health."

29. Under Article 178, paragraph (3) is hereby amended and shall read as follows:

"(3) The manager, natural or legal entity, signs a management contract with the Minister of Public Health or the ministries provided their own sanitary network, as required, for a period of maximum 3 years. The management contract may be terminated ahead of schedule, following an annual assessment carried out in accordance with performance criteria established through Minister of Public Health Order. On expiry of the mandate, the management contract may be extended not more than two times, up to a 3-month period, when a competition examination is held in view of filling in the vacant job. By order, the Minister of Public Health appoints an interim manager up to the filling in of the manager position via competition examination."

30. Under Article 180, paragraph (5) is hereby amended and shall read as follows:

"(5) Individuals in the position of managers of hospitals and other healthcare units with less than 400 beds may carry out a medical activity in the respective institution."

31. Under Article 182, after (1), a new paragraph is introduced, paragraph (2), which reads as follows:

"(2) The competition examination to fill in vacant jobs is organised on hospital level, and it is the manager's duty to undertake appointment of staff members to the respective jobs."

32. Under Article 183, (5) is hereby amended and shall read as follows:

"(5) Members of the Management Board who have been hired through competition examination shall sign an administration contract for no longer than 3 years with the public hospital manager, providing for specific performance indicators as well as the legal norms settling the rights and obligations of parties involved. The administration contract may be extended maximum twice at the end of the mandate for a 3-month period, in which period the competition examination in view of filling in the position is organised. The administration contract ends before the term in case of its demands not being met."

33. Under Article 183, a new paragraph is introduced after paragraph (8), paragraph (9), which reads as follows:

"(9) Provisions of Article 180 (1) b) - d) on incompatibilities and those of Article 180 (2) referring to the conflict of interests is also applicable to persons in Management Board specific positions."

34. Under Article 183^3, a new letter is introduced after letter b), letter b^1), which reads as follows:

"b^1) on demotion of persons in specific positions within the Management Board in case of failure to meet the specific performance indicators mentioned in the administration contract, for at least one year, due to imputable reasons, and/or in case of a serious guilt in consequence of non-fulfilment of their duties".

35. Under Article 183^3, a new letter is introduced after l), letter m), which reads as follows:

"m) non-compliance with staff policy and organisational structure measures of the Minister of Public Health, as required, with measures decided by the minister/manager of the institution for hospitals subordinated to ministries and institutions endowed with their own healthcare network."

36. Under Article 184, (4), (5), (6), (8), (9) and (12) are amended and shall read as follows:

"(4) On assignment to their respective position, heads of section, heads of laboratory or heads of medical services shall sign a three-year administration contract with the public hospital, represented by its manager, contract containing the specific performance indicators. The administration contract may be extended and may be terminated ahead of term, mainly in case of not having met the specific performance indicators. While the administration contract is in force, the potential individual labour contract is suspended. The contract content and its termination methodology shall be established through Minister of Public Health order. If the section/laboratory/medical services head is in a state of incompatibility or conflict of interests, he/she shall eliminate these in no longer than 30 days, under the sanction of unilateral termination of the administration contract.

(5) The position of head of department, head of Laboratory and head of medical service is compatible with an academic position.

(6) In sections, laboratories or clinical medical services, the position of head of section, head of laboratory or head of medical service is held by the highest academic degree, on recommendation of the concerned Senate of the higher medical education institution, with hospital head and Ministry of Public Health approval.

.....

(8) As regards the clinical sections, laboratories and medical services, where there are no employees with higher academic degrees, as well as the non-clinical sections, laboratories and medical services, the requirements for taking part in the competition examination shall be established through a Minister of Public Health Order; as regards hospitals belonging to ministries or institutions having their own healthcare network, the conditions for taking part in the competition examination shall be established through Minister Order, decision of the head of the institution, approved by the Ministry of Public Health. In case no competitor is present at the competition examination within the legal term, the head of the public hospital shall assign another person as head of section, head of laboratory or head of medical service, for a period up to 6 months – meanwhile, the procedures mentioned under paragraph (1) shall be repeated.

(9) The head of section, head of laboratory and head of the medical service shall publicly declare, via affidavit, published on the hospital website, the public healthcare authority website or the Ministry of Public Health website or, as required, on the website of the Ministry of Transportation for subordinated healthcare units, their family connections up

to the 4th degree, including those with staff in the section, laboratory or medical service where they hold the head position.

.....

(12) Under penalty of administration contract termination, provisions of Article 180 (1) b), c) and d) referring to incompatibilities and those of Article 180 (2) referring to the conflict of interests, also apply to heads of section, heads of laboratory and heads of medical services in public hospitals."

37. Article 186 (7) shall be amended as follows:

"(7) Provisions of Article 180 (2) referring to the conflict of interests, shall also apply to the members of the advisory council."

38. Article 190 (2^1) a) shall be amended as follows:

"a) from the state budget, for activities mentioned under (2) a) and b), via the Romanian Academy's budget".

39. Article 200 (2) and (3) shall be amended as follows:

"(2) In view of analysis and evaluation of hospitals belonging to the healthcare networks of ministries or institutions, other than those belonging to the Ministry of Public Health, the commission mentioned under (1) shall be set up through minister order or through order of the head of the institution subordinating the hospital.

(3) As mentioned under (1) and (2), on commission proposal, the head and the advisory councils or the commander/general director, as required, may be revoked through Minister of Public Health or, as required, through order or decision of ministers or heads of institutions endowed with their own healthcare networks."

40. Under Article 200, paragraph (4) is repealed.

41. Under Article 209, paragraph (3) is hereby amended and shall read as follows:

"(3) The management of funds is performed in accordance with the law, via the National Health Insurance House, henceforth the NHIH, through county social insurance health houses, the Defence Health Insurance, Public Order, National Security and Judicial Authority House, henceforth insurance houses. The fund management is also carried out through the Health Insurance House of the Ministry of Transportation, Construction and Tourism up to its reorganisation."

42. Article 210 (1) k) shall be amended as follows:

"k) reimbursement price – the price supported by the Single National Fund of social health insurance for medicinal products, healthcare materials, medical devices and other given to patients throughout the national

healthcare programs. Their list and reimbursement price are approved through Minister of Public Health Order;".

43. Under Article 213 (2), letter a) is repealed.

44. Under Article 227, a new paragraph is introduced after (3), paragraph (4), which reads as follows:

"(4) Remote counselling and diagnosis medical services and their grant are established through the frame agreement."

45. Under article 233, (6) is hereby amended and shall read as follows:

"(6) Medicinal products, healthcare materials, medical devices and other, released through open-circuit pharmacies, which are given to patients as well as the patients included in the national healthcare programs nominated through Government decision are covered at reimbursement price level."

46. Under Article 233, a new paragraph is introduced after paragraph (6), paragraph (7), which reads as follows:

"(7) Medicinal products, healthcare materials, medical devices and other, used in bed containing healthcare units during hospitalisation and for patient specific treatment, as well as for patients covered by national healthcare programs nominated by a Government decision, are acquired at a price which may not exceed the settlement price approved through Minister of Public Health Order, in accordance with the law."

47. Under Article 244, a new paragraph is introduced after (6), paragraph (6^1), which reads as follows:

"(6^1) In view of accomplishing the assessment, providers of medical services, medical devices and medicinal products must pay an assessment tax whose quantum is approved through the methodology mentioned under paragraph (6). Assessment revenues represent own funding revenues."

48. Article 244 (7) shall be amended as follows:

"(7) Funding of assessment activity is provided from revenues in accordance with (6^1)."

49. Article 246 (1) shall be amended as follows:

"Article 246 – (1) Relationships between providers of medical services, medicinal products and medical devices and the insurance houses are of civil nature, represent multi-annual actions and are established and carried out based on a contract. If modification or completion of clauses is necessary, these shall be negotiated and stipulated in additional acts."

50. Article 247 shall be amended as follows:

"Article 247. – Providers of medical services, medicinal products and medical devices shall sign contracts with insurance houses, based on the

models of contracts laid down in the methodological norms for the application of the frame contract, which may also contain other additional clauses, negotiated in accordance with legal provisions in force."

51. Article 249 (1) shall be amended as follows:

"Article 249. – (1) Insurance houses draw contracts with providers of medical services, medicinal products and medical devices, in view of service provision and payment, aiming at financial balance."

52. Article 252 (1) shall be amended as follows:

"Article 252. – (1) Payment of medical services providers may be:

a) in primary medical care and ambulatory specialty care, tariffs per insured persons, tariff per medical service;

b) in medical care in hospitals and other public or private healthcare units, except for ambulatory units, per solved case, tariffs per hospital care day and tariff per medical service;

c) tariffs for certain services as established in the framework contract;

d) reference price provided for in the list of medicinal products with or without personal contribution;

e) reimbursement price for medicinal products, healthcare materials, medical devices and other, ensured within the national healthcare programs on the list approved through Minister of Public Health Order;

f) reference price for certain healthcare services or reference price mentioned provided for in the list of healthcare materials and medical devices or, as required, renting amount for those provided for a established period of time;

g) global budget for public ambulance services."

53. Under Article 257 (2), e) and f) are amended and shall read as follows:

"e) venues from pensions above the limit established for income tax application;

f) venues from lease of property use, venues from dividends and interests, venues from intellectual property rights achieved individually and/or in association with other venues submitted to income tax, only if venues as laid down in a) - e) 2^1 and article 213 (2) h) are not obtained, no less than the monthly gross country average income."

54. Article 257 (3) shall be amended as follows:

"(3) In the case of persons who at the same time receive revenues similar to those mentioned under paragraph (2) a) - e), (2^1) and under Article 213 (2) h), the contribution is calculated in accordance with all these venues."

55. Under Article 257, a new paragraph is introduced after paragraph (2), paragraph (2^1), which reads as follows:

"2^1) In case a person receives tax free venues, the contribution is calculated in accordance with the venues obtained."

56. Article 257 (5) c) shall be amended as follows:

"c) yearly, for what is laid down in (2) c) and f)."

57. Article 257 (7) shall be amended as follows:

"(7) The obligation of transfer of the social health insurance contribution belongs to the legal or natural entity paying the venues laid down in (2) a), d) and e) as well to the insured persons for venues laid down under (2) b), c) and f), respectively."

58. Article 260 (1), b) is hereby amended and shall read as follows:

"b) by the employer or from the insurance fund in case of work accidents and professional diseases, set up in accordance with the law, for the persons mentioned under Article 213 (2) b);".

59. Article 266 (2) and (3) shall be amended as follows:

"(2) The NHIH main object of activity is to ensure consistent and coordinated functioning of the Romanian healthcare social insurance system; its subordinates the county health insurance houses and the Bucharest Health Insurance House, the Health Insurance House of Defence, Public Order, National Safety and the Judicial Authority, as well as the Health Insurance House of the Ministry of Transportation, Construction and Tourism up to its reorganisation.

(3) The NHIH functions based on its own statutes, approved by the administration council and through Government decision. Insurance houses function on the basis of their own statutes, compliant with provisions of the framework statutes, approved by the NHIH administration council, and, in the case of the Health Insurance House of the Ministry of Transportation, Construction and Tourism, with the approval in accordance with the Ministry of Transportation as well. The Health Insurance House of Defence, Public Order, National Safety and the Judicial Authority, carry out their activity in accordance with the functioning and organisation legal provisions of county insurance houses within the insurance healthcare system, while maintaining their specific activity."

60. Under Article 281 (1), 3 new points are introduced after f), namely g), h) and i), as follows:

"g) requires the approval of the Minister of Public Health prior to the submission of the venues and expenses budget of the Ministry of Economics and Finance for the sums transferred from the Ministry of Public Health budget to the budget of the Single National Fund of social health insurance;

h) makes quarterly and yearly reports to the Minister of Public Health on accomplishment of NHIH activities;

i) submits to the Minister of Public Health the regulations proposed within the healthcare policies in view of approval."

61. Under Article 288, a new paragraph is introduced after paragraph (1), paragraph (1^1), which reads as follows:

"(1^1) The general director of the Health Insurance House of the Ministry of Transportation, Construction and Tourism is named following a competition examination organised by the Ministry of Transportation in association with the NHIH, through joint order of the Minister of Transportation and of the NHIH president."

62. Under Article 288, paragraph (4) is hereby amended and shall read as follows:

"(4) The payment and the other rights of the general director are established through the management contract. The base pay is approved by the NHIH president and is established within certain limits, as follows:

a) the minimum limit at the maximum wage level for the position of I A degree counsellor within ministries and other specialised bodies, plus the management allowance (55%) corresponding to the position of general director;

b) the maximum limit in accordance with the law for the position of general secretary within ministries."

63. Under Article 305 (1), a new letter is introduced after a), letter a^1), which reads as follows:

"a^1) failure to submit the statement laid down in Article 215 (3) in due time;".

64. Under Article 306, a new letter is introduced after b), letter b^1), which reads as follows:

"b^1) as provided in a^1), with a 50 - 100 lei penalty;"

65. Under Article 317, paragraphs (1) and (2) are amended and shall read as follows:

"Article 317. – (1) Within 12 months, the Health Insurance House of the Ministry of Transportation, Construction and Tourism shall start a reorganisation process in view of privatisation.

(2) Until the date of reorganisation, the Health Insurance House of the Ministry of Transportation, Construction and Tourism shall carry out its activity in accordance with legal provisions of its organisation and functioning, based on the principle of insurance houses functioning within the healthcare insurance system."

66. Under Article 317, a new paragraph is introduced after (1), paragraph (1^1), which reads as follows:

"(1^1) The Ministry of Transportation is the state representative in the privatisation activity of the Health Insurance House of the Ministry of Transportation, Construction and Tourism."

67. Article 362 is hereby amended and shall read as follows:

"Article 362. – The venues laid down in Article 361, administered by the Ministry of Public Health are used for investments in the infrastructure and endowments in the public healthcare system, national healthcare programs financing, as a reserve for the Ministry of Public Health, as well as for the financing of provision of public emergency medical care."

68. Article 385 (5), (6) and (8) shall be amended as follows:

"(5) In case of public healthcare units with a deficit of medical staff, as well as of public healthcare units in disadvantaged areas, practitioners may carry out their activity beyond the retirement age imposed by the law, up to the filling of positions through competition, on proposal of the public healthcare unit, with the annual approval of the Romanian College of Physicians, through county territorial colleges, and the annual approval of Bucharest City, respectively, and approval of the Ministry of Public Health, the public health authority, respectively, depending on subordination."

(6) Practitioners detained or interned for political reasons, under such circumstances as laid in Article 1 (1) and (2) of Decree-Law No. 118/1990 on grant of certain rights to persons persecuted for political reasons by the dictatorship established as of 6 March 1945, as well as for persons deported abroad or prisoners, republished, as amended, may continue their professional activity, upon request, based on the annual health certificate. These provisions also apply to practitioners who, for political reasons, have been forced to interrupt their education for a given period, therefore obtaining their university degree later on, or to those who have been prevented from resuming their professional activity.

.....

(8) By way of exception from provisions of paragraph (1), physicians legally assigned as holders of rural family medicine offices working under contract with county health insurance houses, may continue under the same terms after becoming of retirement age, upon request, based on an annual agreement by the county public health authority and the Romanian College of Physicians, via the county colleges of physicians, based on the health certificate."

69. Under Article 388, a new paragraph is introduced after (1), paragraph (1^1), which reads as follows:

"(1^1) The term mentioned under (1) may be extended by one month in such situations in which professional recognition is based on the principles of the General Regime for Recognition of Professional Qualifications. In this case, the availability period laid down in (3) shall be prolonged accordingly. "

70. Under Article 484, paragraphs (2) - (5) are amended and shall read as follows:

"(2) In public healthcare units, dental practitioners, full members and corresponding members of the Romanian Academy and of the Academy of Medical Sciences, professors, 1st degree scientific researcher, doctors of medical science, who carry out medical-dental activities, may continue, upon request, their activity until the age of 70. Beyond this age, dentists, full members and corresponding members of the Academy of Medical Sciences may be maintained in their activity in accordance with provisions of Article 10 (2) of Law No. 264/2004 on the organisation and functioning of the Academy of Medical Sciences, as amended. Dentists, full members and corresponding members of the Romanian Academy have the same rights.

(3) Upon request, dentists mentioned under (1) may retire earlier, at the ages laid down in Law No. 19/2000 concerning the public system for pensions and other social insurance rights, as amended, provided they meet requirements for the retirement contribution imposed by the law on early/partial early pension.

(4) Dental practitioners detained or interned for political reasons, under such circumstances as laid down in Article 1 (1) and (2) of the Decree-law No. 118/1990, republished, as amended, may preserved, upon request, in their professional positions, based on the annual healthcare certificate. These provisions also apply to dentists who, for political reasons, have been forced to interrupt their education for a certain period, therefore obtaining their university degree later on, or to those who have been prevented from resuming their professional activity.

(5) In the case of public healthcare units lacking in medical-dental personnel, as well as in the case of public healthcare units located in disadvantaged areas, dentists may continue their activity beyond retirement age imposed by the law, up to the filling of the respective positions through competition, on proposal of the public healthcare unit, with the annual approval of the Romanian Dental Council in Romania and the approval of the Ministry of Public Health, namely of the public health authority, depending on subordination."

71. Under Article 484, a new paragraph is introduced after (3), paragraph (3^1), which reads as follows:

"(3^1) Dentists beyond the age range mentioned under paragraph (1) may continue their practice in private healthcare units. The activity is carried out based on the membership certificate and the annual approval of the Romanian Dental Council, released on the basis of the healthcare certificate and the civil liability insurance for insurance for miscarriage of professional tasks, drawn for the respective year."

72. Under Article 485, a new paragraph is introduced after paragraph (1), namely (1^1), which reads as follows:

"(1^1) The term mentioned under paragraph (1) may be extended by one month in such situations in which professional recognition is based on the principles of the General Regime for Recognition of Professional Qualifications. In this case, the availability period laid down in (3) shall be prolonged accordingly."

73. Under Article 565, paragraphs (2) and (3) are amended and shall read as follows:

"(2) In public healthcare units, pharmacists, full members and corresponding members of the Romanian Academy and of the Academy of Medical Sciences, professors, 1st degree scientific researcher, doctors in pharmaceutical science, who carry out pharmaceutical activities, may continue, upon request, their activity until reaching the age of 70. Beyond the age of 70, pharmacists, full members and corresponding members of the Academy of Medical Sciences, may continue their activity in accordance with provisions of Article 10 (2) of Law No. 264/2004, as amended. Pharmacists, full members and corresponding members of the Romanian Academy have the same right.

(3) Pharmacists mentioned under paragraph (1) may, upon request, retire earlier, at the ages mentioned in Law No. 19/2000, as amended, provided they meet the contribution period conditions enforced by law for the early retirement pension or for the partial early retirement pension."

74. Under Article 565, a new paragraph is introduced after (3), paragraph (3^1), reading as follows:

"(3^1) Pharmacists beyond the age range mentioned under paragraph (1) may continue their practice in private healthcare units. The activity is carried out based of the membership certificate and the annual agreement of the Romanian College of Pharmacists, released on the basis of the healthcare certificate and the civil liability insurance for miscarriage of professional tasks, drawn for the respective year."

75. Under Article 565, paragraph (4) is hereby amended and shall read as follows:

"(4) In case of public healthcare units with insufficient number of pharmacists, as well as of public healthcare units in disadvantaged areas, the pharmacists may continue their activity after the retirement age mentioned in the law, up to the filling of the respective positions through competition, on proposal of the public healthcare unit, with the agreement of the Romanian College of Pharmacists and the approval of the Ministry of Public Health, namely of the public health authority, depending on subordination."

76. Under Article 565, a new paragraph is introduced after paragraph (5), paragraph (6), which reads as follows:

"(6) Pharmacists detained or interned for political reasons, under such circumstances as laid down under Article 1 (1) and (2) of the Decree-Law No. 118/1990, republished, as amended, may be preserved, upon request, in their professional positions based on the annual healthcare certificate. These provisions also apply to pharmacists who, for political reasons, have been forced to interrupt their education for a given period, therefore obtaining their university degree later on, or to those who have been prevented from resuming their professional activity."

77. Article 566 is hereby amended and shall read as follows:

"Article 566. – In hospital pharmacies, the pharmacist is authorised to release medicinal products, healthcare materials, medical devices and such, to hospital sections as well as to their ambulatory insurance, in the context of healthcare programs."

78. Under Article 569, paragraph (1^1) is introduced after paragraph (1), reading as follows:

"(1^1) The term mentioned under paragraph (1) may be extended by one month such situations in which professional recognition is based on the principles of the General Regime for Recognition of Professional Qualifications. In this case, the availability period laid down in (3) is prolonged accordingly."

79. Under Article 661, paragraph (1) is hereby amended and shall read as follows:

"Article 661. – (1) The maximum limits of insurance compensations are established by the NHIH, following consultations with professional associations in the insurance field and the Romanian College of Physicians, the Romanian Railways, the Romanian College of Dentists, the Romanian Order of Medical Assistants, Nurses and Midwives and the Romanian Order of Healthcare Biochemists, Biologists and Chemists, with the approval of the Ministry of Public Health."

80. Under Article 695, points 16 and 34 are amended and shall read as follows:

"16. Wholesale distribution of medicinal products – the sum of activities consisting of acquisition, holding, delivery or export of medicinal products, except for their release to the public (retail distribution); such activities are carried out by manufacturers or their warehouses, importers and other wholesale distributors or by pharmacists or other persons authorised to provide medicinal products to the Romanian public;

.....

34. *Centralised procedure*: marketing authorisation procedure provided in Regulation no. 726/2004 of the European Parliament and Council laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency and in Regulation (EC) No. 1.394/2007 of the European Parliament and of the Council of 13 November 2007 concerning advanced therapy medicinal products.".

81. Under Article 695, a new point is introduced after point 35, point 36, reading as follows:

"36. advanced therapy medicinal product – a product, as defined under Article 2 of Regulation (EC) No. 1.394/2007."

82. Under Article 697 (1), a new letter is introduced after f), letter g), which reads as follows:

"g) advanced therapy medicinal products, as defined in Regulation (EC) No. 1.394/2007, a non-routine basis according to specific quality standards, and used within Romania, in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient."

83. Under Article 697, a new paragraph is introduced after paragraph (1), paragraph (2), which reads as follows:

"(2) The manufacturing of medicinal products mentioned under (1) g) is authorised by the National Medicines Agency, which ensures that traceability and pharmacovigilance requirements as well as specific quality standards mentioned under g) are equivalent to those amended on community level concerning advanced therapy medicinal products for which authorisation is required in accordance with Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 (laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency)."

84. Article 756 is hereby amended and shall read as follows:

"Article 756. – The National Medicines Agency applies provisions of the guidelines published by the European Commission concerning good manufacturing practice, as well as for active substances used as starting materials, concerning the format and content of the authorisation as specified under Article 748 (1), of reports mentioned under Article 823 (3), the format and content of the good manufacturing practice certificate specified under Article 823 (5)."

85. The name of chapter VII "Wholesale distribution of medicinal products" of title XVII "The medicinal product" is hereby amended and reads as follows:

"CHAPTER VII
Distribution of medicinal products"

86. Article 787 is hereby amended and shall have the following content:

"Article 787. – (1) Without prejudice to Article 700, the National Medicines Agency shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorisation has been granted in accordance with the provisions of this Title and with the centralised procedure are distributed on Romanian territory.

(2) Without prejudice to Article 700, the National Medicines Agency shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorisation has been granted in accordance with this Title and with the centralised procedure are distributed on Romanian territory.

(3) Wholesale distribution and storage of medicinal products, as well as their distribution, shall be performed only for medicinal products subject to a marketing authorisation granted by:

a) the European Commission according to centralised procedure; or

b) the National Medicines Agency according to provisions in this Title.

(4) Any wholesale distributor who is not a marketing authorisation holder and who intends to introduce a medicinal product from a Member State shall notify the marketing authorisation holder and the National Medicines Agency thereof; in the case of medicinal products not authorised pursuant to the centralised procedure, notification to the National Medicines Agency is performed without prejudice to additional procedures provided for in Romanian legislation”.

87. Article 788 is hereby amended and shall read as follows:

"Article 788. – (1) The National Medicines Agency shall take all appropriate measures to ensure that the wholesale distribution of medicinal

products is subject to possession of an authorisation to engage in activity as a wholesaler in medicinal products, stating the place for which it is valid.

(2) Where persons authorised to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to authorisation provided for in paragraph (1).

(3) The National Medicines Agency shall take all appropriate measures to ensure that the retail distribution of medicinal products is subject to the possession of an authorisation to engage as a wholesaler in medicinal products, stating the place for which it is valid.

(4) Possession of a manufacturing authorisation shall also include authorisation to distribute by wholesale medicinal products covered by that authorisation; possession of an authorisation to engage in activity as a wholesaler in medicinal products shall not exempt the holder from the obligation to possess a manufacturing authorisation and comply with conditions set out in that respect, even where the manufacturing or import business is secondary.

(5) At the request of the European Commission or any Member State, the National Medicine Agency shall supply all appropriate information concerning individual authorisations granted under paragraph (1).

(6) Checks on the persons authorised to engage in the activity of wholesaler in medicinal products and the inspection of their premises shall be carried out under the responsibility of the National Medicines Agency.

(7) The National Medicines Agency shall suspend or revoke the authorisation referred to in paragraph (1) if the conditions of authorisation cease to be met; the National Medicines Agency shall forthwith inform the Member States and the European Commission thereof.

(8) The National Medicines Agency shall suspend or revoke the authorisation referred to in paragraph (3) if the conditions of authorisation cease to be met.

(9) Should the National Medicines Agency consider that, in respect of a person holding an authorisation granted by a Member State under the terms of Article 77, paragraph (1) of Directive 2001/83/EC, the conditions of authorisation are not, or are no longer met, it shall forthwith inform the European Commission and the Member State involved.

(10) The NMA inspectors may collect samples from the distribution units in view of laboratory analysis.

(11) (10) The costs of samples taken and analyses performed are covered according to Article 823, paragraph (1), point b).

88. Article 789 is hereby amended and shall read as follows:

"Article 789. – (1) The National Medicines Agency shall ensure that the time taken for the procedure for examining the application for the distribution authorisation does not exceed 90 days from the day on which the National Medicines Agency receives the application.

(2) The National Medicines Agency may, if need be, require the applicant to supply all necessary information concerning the conditions of authorisation.

(3) Where the National Medicines Agency notes that not all necessary information has been submitted according to paragraph (2), the period laid down in paragraph (1) shall be suspended until the requisite additional data have been supplied.

89. Under Article 790, a) and b) shall be amended and shall read as follows:

"a) they must have suitable and adequate premises, installations and equipment, so as to ensure proper manufacturing, conservation and distribution of the medicinal products;

b) they must have staff, and in particular, a qualified person designated as responsible for the quality of medicinal products, meeting the conditions provided for by Romanian legislation;

90. Under Article 791, c), d), f) and g) are amended and shall read as follows:

"c) they must supply medicinal products only to persons who are themselves in possession of the distribution authorisation or who are authorised by the National Medicines Agency to supply medicinal products to the public in Romania;

d) they must have an emergency plan which ensures effective implementation of any recall from the market ordered by the National Medicines Agency or carried out in cooperation with the manufacturer or marketing authorisation holder for the medicinal product concerned;

f) they must keep the records referred to under e) available to the National Medicines Agency, for inspection purposes, for a period of five years;

g) they must comply with the principles and guidelines of good distribution practice for medicinal products, as well as with the good pharmaceutical practice rules for medicinal products, as laid down in Article 795."

91. Under Article 792, (1) and (2) are amended and shall read as follows:

"Article 792. – (1) With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal

products to the public, the National Medicines Agency shall not impose upon the holder of a distribution authorisation which has been granted by a Member State, any obligation, in particular public service obligations, more stringent than those imposed on persons authorised to engage in equivalent activities in Romania.

(2) The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in Romania shall ensure, within the limits of their responsibilities, appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in Romania are covered."

92. Under Article 793, (2) is hereby amended and shall read as follows:

"(2) The National Medicines Agency shall take all appropriate measures to ensure that persons authorised to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product."

93. Article 794 is hereby amended and shall read as follows:

"Article 794. – The provisions of this Chapter shall not prevent the application of more stringent requirements in respect of the wholesale distribution of:

a) narcotic or psychotropic substances within Romanian territory;

b) medicinal products derived from blood;

c) immunological medicinal products;

d) radiopharmaceuticals.

94. Article 795 is hereby amended and shall read as follows:

"Article 795. – The National Medicines Agency shall monitor the application of good distribution practice guidelines published by the European Commission, as well as the application of good pharmaceutical practice guidelines imposed by law."

95. Article 836 is hereby amended and shall read as follows:

"Article 836. – (1) The following shall constitute offences and shall be sanctioned as follows:

a) a fine of 10,000 RON to 30,000 RON and closure of the unit shall be applied in cases of manufacturing unit functioning not based on possession of a manufacturing authorisation granted by the National Medicines Agency; the same fine and closure of the unit shall be applied in the case of wholesale distribution units functioning not based on possession of an authorisation granted by the National Medicines Agency;

b) a fine of 5,000 RON to 10,000 RON shall be applied, in case of disregard of good laboratory practice by laboratories carrying out pharmaco-toxicological testing in view of gathering documentation for marketing authorisation of a medicinal product for human use;

c) a fine of 5,000 RON to 10,000 RON shall be applied to the manufacturer or distributor, as appropriate, in case of: conducting, within their premises, of activities other than those they have been authorised for; distribution of medicinal products from the manufacturer or wholesale distributors to units not authorised by the National Medicines Agency according to the law; participation in the manufacturing and distribution process involving technical operations which require specialised training, of staff not appropriately qualified, as well as violation of provisions on medicinal products classification for supply, labelling and package leaflet, medicinal product advertising, reporting of changes in manufacturing and distribution, withdrawals, infringement of good pharmacovigilance practice by the marketing authorisation holder;

d) a fine of 5,000 RON to 10,000 RON shall be applied for infringement of conditions based on which the medicinal product has been authorised for manufacture or of good manufacturing practice;

e) a fine of 10,000 RON to 20,000 RON shall be applied in case of medicinal products are manufacture and distribution in the absence of documents certifying their origin and/or quality, in case of infringement of provisions regarding medicinal products withdrawal by manufacturers or distributors as well as in the case of possession or distribution of medicinal products whose shelf life is overdue or whose analysis bulletin is noncompliant;

f) a fine of 5,000 RON to 10,000 RON shall be applied for absence of the chief pharmacist or alternate from the distribution unit premises during unit functioning time as well as for obstruction of inspection activities;

g) a fine of 10,000 RON to 30,000 RON and one year suspension of the functioning authorisation for the distribution unit shall be applied in case one of the violations referred to under c) and e) is repeated within 3 months.

h) a fine of 5,000 RON to 20,000 RON and suspension of functioning authorisation of the distribution unit until remedy of the reported deficiencies shall be applied in case of infringement of good distribution practice.

i) a fine of 2,000 to 5,000 RON shall be applied in case the marketing authorisation holder does not meet the requirements or restrictions included in the marketing authorisation concerning the release or use of the medicinal product, as well as those referring to the safe and efficient use of

the medicinal product, in case of failure to report to the National Medicines Agency adverse reactions or submit the updated periodic reports on the safety of medicinal products, modifications (variations) to the terms of the marketing authorisations, failure to notify the National Medicines Agency on the actual trade date or the date of the medicinal product marketing cessation, failure to provide to the Ministry of Public Health or, as required, to the National Medicines Agency, data concerning the volume of medicinal product sales and prescriptions, in accordance with the provisions of this title;

j) a fine of 2,000 to 5,000 RON shall be applied in case independent laboratories or laboratories acknowledged by the National Medicines Agency fail to meet the conditions in which the authorisation has been granted;

k) a fine of 2,000 to 5,000 RON shall be applied in case of importers who break their commitment concerning transmission to the National Medicines Agency of the exact situation of each import, in accordance with legal provisions;

l) a fine of 5,000 to 10,000 RON shall be applied in case of failure to submit, within 6 months as of their ending, of any trials sponsored by the marketing authorisation holder implying paediatric use of a medicinal product covered by a marketing authorisation, regardless of whether their conduct in accordance with an agreed paediatric investigation plan.

(2) Ascertaining of offences and enforcement of sanctions referred to in paragraph (1) are performed by inspectors of the National Medicines Agency.

96. Article 848 is hereby amended and shall read as follows:

"Article 848. – The National Medicines Agency shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired."

97. Article 851 is hereby amended and shall read as follows:

"Article 851. – The Ministry of Public Health shall establish and approve, by Minister of Public Health Order, the maximum prices of medicinal products except for non- prescription medicinal products (OTC)."

98. Article 856 is hereby amended and shall read as follows:

"Article 856. – On submission of documentation for functioning authorisation, distribution units shall pay the tariff for the functioning authorisation, approved through Minister of Public Health Order, to the account of the National Medicines Agency."

99. Article 858 is hereby amended and shall read as:

"Article 858. – Expenses required for inspections by National Medicines Agency employees with a view to granting a functioning authorisation or other types of inspections shall be ensured from the budget of the National Medicines Agency."

Article II. – The deadline laid down under Article 317 (1) of Law No. 95/2006, as amended, concerning the reorganisation process in view of privatisation of the Ministry of Transportation, the Health Insurance House of the Ministry of Transportation, Constructions and Tourism starts as of the date of this emergency ordinance coming into force.

Article III. – (1) The set up of institutions under Article 11 b) of Law No. 95/2006, as amended, with attributions in the fields of medical care, national healthcare programs, healthcare infrastructure and public health control, is carried out through reorganisation of the Ministry of Public Health, of county and Bucharest public health authorities, as well as of public healthcare institutions and centres.

(2) On the date of the coming into force of Government decisions allowing for functioning of institutions mentioned under (1), Article 12, article 13 (1), Article 17(1) and (2), Article 18 - 23 and Article 24 (2) are repealed.

(3) On the same date when the institutions mentioned under (1) start to function, phrases such as "county and Bucharest city public health authorities " and "territorial public health authorities" are replaced by the phrase "institutions carrying out activities in the public healthcare field which undertake their attributions".

(4) Throughout the entire Title II "National healthcare programs", phrases such as "The National Program Agency" and "The National Agency for Healthcare Programs" are replaced by the phrase "structure with duties in the set up and coordination of national healthcare programs".

(5) Up to the date laid down in (2), when institutions laid down in (1) start their activity, the attributions of the structure laid down in (4) are carried out by the National Agency for Healthcare Programs, as a structure belonging to the Ministry of Public Health with duties in the set up and coordination of national healthcare programs.

Bucharest, 24 June 2008.
No. 93.