LAW 132
of 9 October 2014
on approval of Emergency Government Ordinance no. 2/2014 on amendment of Law 95/2006 on healthcare reform and of certain regulatory acts

ISSUED BY: THE PARLIAMENT
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The Parliament of Romania hereby adopts this Law.

ARTICLE I

Emergency Government Ordinance no. 2 of 29 January 2014 on amendment of Law 95/2006 on healthcare reform and of certain regulatory acts, published in the Official Gazette of Romania, Part I, no. 104 of 11 February 2014, is approved as amended:

1. Under Article I point 3, paragraph (2) of Article 4 is amended as follows:

"(2) In line with provisions of this Law, ministries and institutions provided with healthcare networks of their own are authorities and institutions with subordinated healthcare facilities, other than the Ministry of Health, namely the Ministry of National Defence, the Ministry of Internal Affairs, the Ministry of Justice, the Ministry of Transport, the Romanian Intelligence Service, the Foreign Intelligence Service, the Special Telecommunication Service, the Romanian Academy, local public administration authorities, accredited medicine and pharmacy universities and universities with accredited medicine and pharmacy faculties."

2. Under Article I, points 7, 13, 18, 19, 23, 25, 26, 28, 30, 52, 54, 86 and 91 shall be repealed.

3. Under Article I point 11, Article 16 (1^1) is amended as follows:

"(1^1) In conduct of its duties and responsibilities mentioned under (1), the Ministry of Health and its special structures shall have full access to and make use of data of the Health Insurance Information Platform, in line with provisions of Law no. 677/2001 on the protection of individuals with regard to personal data processing and free movement, as amended. The National Health Insurance House (NHIH) and the provider of the Health Insurance Information Platform shall grant the Ministry of Health the same access rights and privileges to information data as granted to the NHIH."

4. Under Article I, a new point, 12^1, is introduced after point 12, which reads as follows:

"12^1. Under Article 16(1), a new point, j), is introduced after point i), which reads as follows:

«j) funding, according to the budget available in this respect, scientific research activities in the medical field, as included in the sectoral plan, as approved through Order of the Minister of Health.»"

5. Under Article I (20), paragraphs (1), (2) and (4) of Article 47 are amended as follows:

"ARTICLE 47

(1) National healthcare programmes are set up by the Ministry of Health through a specialised structure, established through Government Decision.

(2) For set up of national healthcare programs, the specialised structure collaborates with the NHIH and authorities, institutions and non-governmental organisations.

.....

(4) In case of epidemiological risk, beneficiaries of national healthcare programmes, whose purpose is to prevent, monitor and control communicable diseases, are persons mentioned under (3), as well as transients in Romania."

6. Under Article I, point 21 is amended as follows:

"21. On 1 August 2014, paragraph (4) of Article 48 shall be repealed."

7. Under Article I, point 22 shall be repealed.

8. Under Article I, point 24 shall be repealed.

9. Under Article I, point 27 shall be repealed.

10. Under Article I, point 29 shall be repealed.

11. Under Article I, point 31 shall be repealed.

12. Under Article I, a new point, 36^1, is introduced after point 36, which reads as follows:

"36^1. Under Article 93, paragraph (4) is amended as follows:

«(4) Amounts required for management of critical cases whose costs cannot be covered from funds obtained from contracts with health insurance houses shall be covered from Ministry of Health funds, state budget funds and personal revenues."

13. Under Article I point 39, Title V^1, "Special outpatient medical assistance" Chapter I, Article 128^1 paragraph (1), point e) is amended as follows:

"e) outpatient medical facilities of accredited medicine and pharmacy universities with accredited medicine and pharmacy faculties."

14. Under Article I, after point 40, two new points are added, points 40^1 and 40^2, which read as follows:

"40^1. Under Article 148, paragraph (16) is amended as follows:

«(16) The health inspection structure of the Ministry of Health and public health control structures on county level and Bucharest health directorates coordinate and organise the vigilance system mentioned under (15) for notification of severe adverse events and severe adverse reactions in human cells and tissues used for therapeutic purposes.»

40^2. Under Article 148, a new paragraph, (16^1), is introduced after paragraph (16), which reads as follows:

«(16^1) The National Transplant Agency coordinates and organises the vigilance system mentioned under (15) for notification of severe adverse events and severe adverse reactions in human organs used for therapeutic purposes.»"

15. Under Article I point 44, paragraph (3) of Article 170 is amended as follows:

"(3) Expenses of hospital facilities, in the cases mentioned under (2), are reimbursed from the state budget, through budgets of the ministries, of management structures, as well as through the budget of administrative-territorial structures, the budgets of universities of medicine and pharmacy, as required, through Government Decision, within maximum 30 days as of date of cessation of the underlying cause."

16. Under Article I point 45, paragraphs (2^1) and (2^2) of Article 174 are amended as follows:

"(2^1) Management of medical care provided in public hospitals may be transferred to local public administration authorities, accredited state medicine and pharmacy universities, universities with accredited state medicine and pharmacy universities, through Government Decision, initiated by the Ministry of Health, on proposal by local public administration authorities, accredited state medicine and pharmacy universities, universities with accredited medicine and pharmacy faculties, as required.

(2^2) Buildings of public hospitals mentioned under (2^1) may be given for administration to local public administration authorities, accredited state universities for medicine and pharmacy, universities with accredited medicine and pharmacy faculties, in accordance with the law."

17. Under Article I, a new point, 45^1, is introduced after point 45, which reads as follows:

"45^1. Under Article 178 paragraph (2), the introductory paragraph is amended as follows:

«(2) The manager (natural entity) or the representative appointed by the manager (legal entity) is a graduate from medical/economic-financial/legal upper education institutions and shall meet one of the following conditions:».

18. Under Article I point 46 a) of paragraph (2) of Article 178 is amended as follows:

"a) to have specialised training in management/healthcare management, approved by the Ministry of Health and established through Order of the Minister of Health;".

19. Under Article I point 47, paragraph (3) of Article 178 is amended as follows:

"(3) The manager, physical or legal entity, signs management contracts with the Ministry of Health, ministries or institutions with healthcare networks of their own, represented by the Minister of Health, the head of the Ministry or institution, dean of the university of medicine/pharmacy, as required, for

maximum 3 years. The management contract may be terminated in advance following annual assessment or whenever needed. Assessment is performed according to overall performance criteria established through Order of the Minister of Health, as well as according to specific criteria and averages established and approved through administrative action of the heads of ministries or institutions with healthcare networks of their own, of the head of the territorial-administrative unit, the Mayor of Bucharest or the President of the County Council or by decision of the Senate of the university of medicine and pharmacy, as required. Following evaluation, the administration board shall contact external experts/auditors responsible for verification of accomplishment of general and specific criteria specified in the management contract, by approval of the credit officer and in accordance with legal provisions in force. According to the external audit, the administration board may require the manager to implement corrective measures or may decide upon termination of the management contract. When the mandate is suspended, the management contract may be prolonged for a 3-month period, not more than two times, for the period required for organisation of the employment competition, or public auction, as required. The minister of health, the representative minister or the mayor of the administrative-territorial unit, the mayor of Bucharest, the President of the County Council or the Dean of the University of Medicine and Pharmacy, as required, issue an administrative act assigning an interim manager until employment of a new manager or organisation of the public auction, as required. Implementation rules on auditing and legal advice are issued by the Ministry of Health and approved through Order of the Minister of Health."

20. Under Article I point 48, paragraph (1) of Article 179 is amended as follows:

"ARTICLE 179

(1) The Administration board organises a competition or public auction, as required, in order to select the manager/legal person able to ensure the management of the healthcare unit, in accordance with the norms approved through Order of the Minister of Health or, as required, through Order of the Minister from ministries provided with their own healthcare networks and through administrative act of the mayor of the administrative-territorial unit, the mayor of Bucharest or the President of the county council, the dean of the university of medicine and pharmacy, as required. The Administration board must contract external experts for proper performance of the competition/auction, assessment of the management plan and manner of accomplishment (through management plan) of general and specific performance criteria, in accordance with the chief credit accountant and legal provisions in force."

21. Under Article I, two new points, 53^1 and 53^2, are introduced after point 53, which read as follows:

"53^1. Under Article 190 paragraph (3), point a) is amended as follows:

«a) from the state budget, as regards the situation mentioned under (2) b), d) and e) through budget of the Romanian Academy and, by exemption from provisions of Article 47 (6) of Law 500/2002 on public finances, as amended, through budget transfer from the Ministry of Health to the Romanian Academy, based on signed contract between chief credit accountants;».

53^2. Under Article 190, a new paragraph, (3^1), is introduced after (3), which reads as follows:

«(3^1) Financing of the Elias Emergency University Hospital, as stipulated under (3) a), may also be ensured from local budgets, according to budget credits approved for this purpose in the frame of local budgets.»"

22. Under Article I point 55, paragraph (2) of Article 190^3 is amended as follows:

"(2) Amounts required to perform agreements mentioned under Article 190^1 a) and e) are ensured from state budget funds and from personal revenues, through budget of the Ministry of Health."

23. Under Article I point 56, Article 190^5 is amended as follows:

"ARTICLE 190^5

(1) Public hospitals from the network of local public administration authorities can be paid from the state budget and the revenues of the Ministry of Health, allocated through transfer based on contracts signed between public health directorates and health directorate of Bucharest and local public administration authorities to whom the respective facilities subordinate, for:

a) finalisation of new investment objectives, ongoing investments, investments financed, prior to the date of transfer of public hospital management, through yearly investment programs of the Ministry of Health;

b) supply with medical equipment, taking into account that local public administration authorities participate to this purchase with funds amounting to minimum 10% of their value;

c) major hospital rehabilitation, taking into account that local public administration authorities participate to this purchase with funds amounting to minimum 5% of their value;

d) funding of objectives related to refurbishment, transformation and extension of existing buildings and of inspection, design and consolidation of buildings, if local public administration authorities cooperate in payment with funds of minimum 10% of their value.

(2) Amounts allocated from the budget of the Ministry of Health mentioned under (1) b), c) and d), as well as the list of beneficiary public hospitals are submitted to yearly approval through Government Decision, after publication of the State Budget Law.

(3) The Orders mentioned under (2) are approved according to proposals of special structures of the Ministry of Health following requests from local public administration authorities."

24. Under Article I, a new point, 59^1, is introduced after point 59, which reads as follows:

"59^1. Under Article 210 paragraph (1), a new point, k), is introduced after point j), which reads as follows:

«k) reimbursement price – price paid from the Single national fund for social health insurance for medicinal products, health materials, medical devices and such released through closed circuit pharmacies for insured persons included in national healthcare programs. Their List and reimbursement price are approved through joint Order of the Minister of Health and of the NHIH president.»"

25. Under Article I point 65, paragraphs (2) and (4) of Article 217 are amended as follows:

(2) Rights mentioned under (1) are stablished based on a multiannual framework contract, elaborated by the NHIH following consultation with the Romanian College of Physicians, hereinafter RCP, the Romanian College of Dentists, hereinafter RCD, the Romanian College of Pharmacists, hereinafter RCP, the Romanian Order of Medical Assistants, Nurses and Midwives, hereinafter ROMANM, the Romanian Order of Healthcare Biochemists, Biologists and Chemists, hereinafter ROHBBC, as well as with representative patronal, union and professional healthcare organisations. The project is approved by the Ministry of Health through Government Decision, within 60 days as of approval of the State Budget Law for the year awaiting approval of a new framework agreement.

.....

(4) The NHIH prepares implementation rules for application of the framework agreement, in collaboration with the RCP, RCD, ROMANM, ROHBBC, RCP, as well as with representative patronal, union and professional healthcare organisations, approved through Order of the Minister of Health and through Order of the NHIH president, within 30 days as of publication of the Government Decision mentioned under (2)."

26. Under Article I point 84, point c) of Article 238 is amended as follows:

"c) supplier compliance with quality criteria for medical and dental assistance, elaborated by the Ministry of health and the CNA."

27. Under Article I, a new point, 84^1, is introduced after point 84, which reads as follows:

"84^1. A new Article, 239, is introduced after Article 239^1, which reads as follows:

«ARTICLE 239^1

The NHIH and health insurance houses organise the control of healthcare activities in order to maintain the quality of medical services provided for insured persons, according to the criteria mentioned under Article 238 c) and Article 239.»"

28. Under Article I point 87, Article 242 is amended as follows:

"ARTICLE 242

Medicinal products granted by outpatient facilities within the national healthcare programs (national therapeutic healthcare programs) are ensured through pharmacies belonging to healthcare facilities where provided or through other pharmacies, as the case may be."

29. Under Article I point 89, Article 244 is amended as follows:

"ARTICLE 244

(1) Providers of healthcare services, medicinal products and medical devices, meeting the assessment criteria established by the NHIH and the Ministry of Health, may enter a contractual relationship with health insurance houses.

(2) The assessment process involves medical cabinets, special outpatient facilities, hospitals, pharmacies, providers of medical care at home, providers of medical devices, private providers of emergency consultations at home and unassisted health transportation, as well as other physical or legal persons authorised in this respect by the Ministry of Health.

(3) The assessment of medical service providers, medicinal products and medical devices mentioned under (2), is performed at national/county level.

(4) Assessment commissions of providers of medical services, medical devices and medicinal products at national level are made of representatives of the Ministry of Health and of the NHIH; at county level, assessment commissions are made of county and Bucharest representatives of public health directorates and representatives of health insurance houses and, as required, of ministries and institutions with their own health networks.

(5) The regulation for operation of commissions assessing providers of medical services, medical devices and medicinal products, as specified under paragraph (2), is set up by national commissions and approved through Order of the Minister of Health and Order of the NHIH president. Assessment standards issued by national assessment commissions are approved through Order of the Minister of Health and Order of the NHIH president.

(6) The methodology and level of assessment of providers of medical services, medical devices and medicinal products, as specified under paragraph (2), are set up and established by commissions organized at national level and approved through Order of the Minister of Health and Order of the NHIH president.

(7) In view of performing the assessment process, providers of medical services, medicinal products and medical devices are required to pay an assessment tax whose quantum is approved through the Order mentioned under (6).

Venues obtained after assessment activities become own revenues to the fund."

(8) Termination of the assessment activity is supported from venues obtained in line with paragraph (7)."

30. Under Article I, a new point, 91^1, is introduced after point 91, which reads as follows:

"91^1. A new Article, 253^1, is introduced after Article 253, which reads as follows:

«ARTICLE 253^1

Medical assistance and medical care at the residence of the insured person are contracted by health insurance houses with authorised suppliers according to the Law.»"

31. Under Article I point 106, paragraph (2) of Article 262^1 shall be repealed.

32. Under Article I point 107, paragraph (2^1) of Article 265 shall be repealed.

33. Under Article I, a new point, 110^1, is introduced after point 110, which reads as follows:

"110^1. Under Article 275, point a) shall be repealed."

34. Under Article I, a new point, 111^1, is introduced after point 111, which reads as follows:

"111^1. Under Article 279 paragraph (1), point g) is amended as follows:

«g) approves the individual status of the NHIH, as approved through Government decision, and the frame status of insurance houses, upon request of the steering committee;»".

35. Under Article I, a new point, 117^1, is introduced after point 117, which reads as follows:

"117^1. Under Article 313, paragraph (1) is amended as follows:

«ARTICLE 313

(1) Persons whose deeds are detrimental to other person’s health, as well as to their own, are legally liable and shall repair harm done to the medical service supplier by covering actual costs incurred by medical care provided. Amounts representing actual costs are recovered by medical service suppliers. As regards litigations for recovery of such amounts, medical service suppliers may substitute as concerns all procedural rights and obligations of health insurance houses and gain their procedural quality in all trials and requests related to courts of jurisdiction, regardless of trial stage.»"

36. Under Article I, a new point, 120^1, is introduced after point 120, which reads as follows:

"120^1. Under Article 362, point a) is amended as follows:

«a) investments in infrastructure and subsidies for public facilities in the network of the Ministry of Health and public hospitals in the network of the local public administration authority, in line with conditions established in Article 190^5 (1);».

37. Under Article I, a new point, 121^1, is introduced after point 121, which reads as follows:

"121^1. Under Article 370, paragraph (2) is amended as follows:

«(2) By exemption from provisions of Article 371 (1), (3) d) and Article 372, physicians who are citizens of a third state may perform professional activities in Romania for educational purpose and occasionally by permission of the Romanian College of Physicians. In such cases, professional activities may be conducted over a 3-month duration, with possibility of extension to no longer than 3 months per year. The methodology for approval is adopted through Decision of the National Council of the Romanian College of Physicians and is published in the Official Gazette of Romania, Part I.»"

38. Under Article I, a new point, 121^2, is introduced after point 121^1, which reads as follows:

"121^2. Under Article 375, paragraph (2) is amended as follows:

«(2) Considering the nature of the physician status and the physician's main duties toward patients, the physician is not a civil servant and may not be assimilated to civil servant status.»"

39. Under Article I, point 122 shall be repealed.

40. Under Article I, 5 new points, 122^1, 122^2, 122^3, 122^4 and 122^5, are introduced after point 122, which read as follows:

"122^1. Under Article 392, paragraph (2) is amended as follows:

«(2) On a case-by-case basis, the Romanian College of Physicians decides on the temporary or occasional character of provision of physician-related activities, depending on their duration, frequency, periodicity and continuity.»

122^2. Under Article 393, paragraph (2) is amended as follows:

«(2) They are automatically registered with the Romanian National College of Physicians during conduct of the respective services, based on documents mentioned under Article 396, submitted by the provider.»

122^3. Under Article 396, paragraphs (1) and (2) are amended as follows:

«ARTICLE 396

(1) Requests of physicians who are citizens of a EU member state/the EEA/the Swiss Confederacy residing in one of these states, on temporary/occasional provision of services in Romania, are processed by the Romanian College of Physicians.

(2) If, for temporary provision of medical services, this is the applicant's first visit to Romania or in case of documented material changes in the applicant's status, the applicant shall submit the following to the College of Physicians:

a) a preliminary written declaration, stating the applicant's field of insurance or other means of personal/collective protection for professional liability in their member state of residence;

b) a copy of the citizenship document;

c) a declaration attesting knowledge of the Romanian language, required for work in Romania;

d) proof of attestation by competent authorities of the member state of residence that the holder has not been subject to temporary or final suspension from conduct of their profession or to criminal convictions ;

e) the diplomas, certificates or other medical titles as stipulated by the law or by European Union norms for conduct of activities concerned;

f) certified translation into Romanian of documents mentioned under c), d) and e).»

122^4. A new Article, 396^1, is introduced after Article 396, which reads as follows:

«ARTICLE 396^1

(1) As regards first provision of services, for physicians educated in a Member State of the European Union, whose professional training does not meet the criteria for automatic recognition established by the Rules for recognition of diplomas, certificates and titles of physician, dentist, pharmacist, general medical assistant and midwife, released by a Member State of the European Union, by a state of the European Economic Area or by the Swiss Confederacy, the Romanian College of Physicians may perform an assessment of the provider's professional qualifications.

(2) Preliminary check is possible, only for avoidance of potential serious harm to the patient's health resulting from providing physician's lack of professional qualification and as long as it does not exceed necessities in that respect.

(3) Within 1 month after receipt of the declaration and attached documents, the Romanian College of Physicians informs the providing physician about:

a) its decision not to check the provider's qualifications; or

b) following assessment of professional qualifications, to require a passing score from the providing physician in a capability test or inform him/her on its decision to allow provision of the respective services.

In case of difficulties possibly resulting in delayed response, in advance of the end of the first month after receipt of the declaration and its attached documents, the Romanian College of Physicians informs the providing physician, on the grounds for delay, as well as on the time required to make a decision. Difficulties are solved within one month after notification and the decision is made within two months after resolution of the difficulty.

(4) In case of major differences between providing physician's professional qualifications and specific training required in Romania for supply of the respective medical services, to the extent to which such difference may adversely impact public safety or health and cannot be compensated by the providing physician's professional experience or the knowledge, abilities and competences acquired through lifelong learning, officially validated in this respect by a relevant body, the Romanian College of Physicians provides the applicant an opportunity to demonstrate, by taking a capability test, as

mentioned under (3) b), the acquisition of required knowledge, abilities and competences.

(5) After the capability test, the Romanian College of Physicians decides whether the providing physician may perform the medical service in question.

(6) Supply of services must be feasible within one month after adoption of the Decision in accordance with provisions of par. (5).

(7) The Romanian College of Physicians failing to respond, as established under paragraphs (3) and (4), the respective services may be performed.»

122^5. A new Article, 396^2, is introduced after Article 396^1, which reads as follows:

«ARTICLE 396^2

Every six months, the Romanian College of Physicians reports the number of physicians beneficiary of provisions of Articles 396 and 396^1 to the Ministry of Health.»"

41. Under Article I, five new points, 123^1, 123^2, 123^3, 123^4 and 123^5, are introduced after point 123, which read as follows:

"123^1. Under Article 488, paragraph (2) is amended as follows:

«(2) On a case-by-case basis, the Romanian College of Dentists decides on the temporary or occasional character of provision of dentist activities, depending on their duration, frequency, periodicity and continuity.»

123^2. Under Article 492, paragraphs (1) and (2) are amended as follows:

«ARTICLE 492

(1) Requests of dentists who are citizens of a EU member state/the EEA/the Swiss Confederacy residing in one of these states, on temporary/occasional provision of services in Romania, are processed by the Romanian College of Dentists.

(2) If, for temporary provision of medical services, this is the applicant's first visit to Romania or in case of documented material changes in the applicant's status, the applicant shall submit the following to the Romanian College of Dentists:

a) a preliminary written declaration, stating the applicant's field of insurance or other means of personal/collective protection for professional liability in their member state of residence;

b) a copy of the citizenship document;

c) a declaration attesting knowledge of the Romanian language, required for work in Romania;

d) proof of attestation by competent authorities of the member state of residence that the holder has not been subject to temporary or final suspension from conduct of their profession or to criminal convictions;

e) the diplomas, certificates or other medical titles as stipulated by the law or by European Union norms for conduct of activities concerned;

f) certified translation into Romanian of documents mentioned under c), d) and e).»

123^3. A new Article, 492^1, is introduced after Article 492, which reads as follows:

«ARTICLE 492^1

(1) As regards first provision of services, for physicians educated in a Member State of the European Union, whose professional training does not meet the criteria for automatic recognition established by the Rules for recognition of diplomas, certificates and titles of physician, dentist, pharmacist, general medical assistant and midwife, released by a Member State of the European Union, by a state of the European Economic Area or by the Swiss Confederacy, the Romanian College of Dentists may perform an assessment of the provider's professional qualifications.

(2) Preliminary check is possible, only for avoidance of potential serious harm to the patient's health resulting from providing physician's lack of professional qualification and as long as it does not exceed necessities in that respect.

(3) Within 1 month after receipt of the declaration and attached documents, the Romanian College of Dentists informs the providing physician about:

a) its decision not to check the provider's qualifications; or

b) following assessment of professional qualifications, to require a passing score from the providing physician in a capability test or inform him/her on its decision to allow provision of the respective services.

In case of difficulties possibly resulting in delayed response, in advance of the end of the first month after receipt of the declaration and its attached documents, the Romanian College of Dentists informs the providing physician, on the grounds for delay, as well as on the time required to make a decision. Difficulties are solved within one month after notification and the decision is made within two months after resolution of the difficulty.

(4) In case of major differences between providing physician's professional qualifications and specific training required in Romania for supply of the respective medical services, to the extent to which such difference may adversely impact public safety or health and cannot be compensated by the providing physician's professional experience or the knowledge, abilities and competences acquired through lifelong learning, officially validated in this respect by a relevant body, the Romanian College of Dentists provides the applicant an opportunity to demonstrate, by taking a capability test, as mentioned under (3) b), the acquisition of required knowledge, abilities and competences.

(5) After the capability test, the Romanian College of Dentists decides whether the providing physician may perform the medical service in question.

(6) Supply of services must be feasible within one month after adoption of the Decision in accordance with provisions of par (5).

(7) The Romanian College of Dentists failing to respond, as established under paragraphs (3) and (4), the respective services may be performed. Supply

of services is performed according to professional title, as stipulated by the law.»

123^4. A new Article, 492^2, is introduced after Article 492^1, which reads as follows:

«ARTICLE 492^2

Every six months, the Romanian College of Dentists reports the number of physicians beneficiary of provisions of Articles 492 and 492^1 to the Ministry of Health.»

123^5. Under Article 683, paragraph (1^1) is amended as follows:

«(1^1) The SNSPMPDSB is a Romanian public legal entity, entirely self-funded, under coordination of the Ministry of Health; academic coordination is established through Government decision. The SNSPMPDSB operates according to economic administration and financial autonomy; it calculates depreciations and conducts economic management of accounts.»"

42. Under Article I point 124, point 17 of Article 695 is amended as follows:

"17. *Public service obligation*: the obligation placed on marketing authorisation holders/representatives marketing authorisation holders and wholesale authorisation holders to permanently ensure an adequate range of medicinal products properly meeting requirements of a specific geographical area, as established and justified by the Ministry of Health, and deliver supplies requested over the entire area in question within the shortest time possible after order."

43. Under Article I, a new point, 126^1, is introduced after point 126, which reads as follows:

"126^1. Under Article 750, paragraph (1) is amended as follows:

«ARTICLE 750

(1) The National Medicines Agency only grants the manufacturing authorisation after ascertaining the accuracy of the information supplied pursuant to Article 749, by means of an inspections carried out by its inspectors."

44. Under Article I point 127, paragraph (6) of Article 787 is amended as follows:

"(6) For medicinal products reimbursed in the frame of the national healthcare insurance system, the marketing authorisation holder or their representative in Romania shall take all measures required for wholesale distribution of these medicinal products through at least three authorised wholesale distributors, except for medicinal products supplied in accordance with Order of the Minister of Health."

45. Under Article I, five new points, 127^1, 127^2, 127^3, 127^4 and 127^5, are introduced after point 127, which read as follows:

"127^1. Under Article 788, paragraph (2) is amended as follows:

«(2) Under national law, legal persons authorised to supply medicinal products to the public may not engage in wholesale distribution business as well.»

127^2. Under Article 791, point b) is amended as follows:

«b) only set up their medicinal product supply stocks from persons themselves in possession of the distribution authorisation or who are exempt from obtaining such authorisation under the terms of Article 788, paragraph (4);

127^3. Under Article 791, a new point, j), is introduced after point i), which reads as follows:

«j) to monthly report to the National Agency for Medicines and Medical Devices the record mentioned under e), under conditions established through Order of the Minister of Health.».

127^4. Under Article 792, paragraph (2) is amended as follows:

« (2) Marketing authorisation holders /their representative and wholesale distributors of the said medicinal product actually placed on the market in Romania shall ensure, within their responsibilities, appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products, so as to cover needs of patients in Romania in accordance with provisions of the Order of the Minister of Health; ».

127^5. Article 795 is amended as follows:

«ARTICLE 795

(1) The National Agency for Medicines and Medical Devices shall monitor the application of guidelines on good distribution practice, which are published by the European Commission.

(2) It is the duty of the Ministry of Health to monitor application of Good Pharmaceutical Practice Guidelines stipulated by the law.»"

46. Under Article I point 129, paragraph (1) of Article 799^1 is amended as follows:

"ARTICLE 799^1

(1) Manufacturers, marketing authorisation holders or their representatives to Romania and wholesale and retail distributors of medicinal products, medical devices and healthcare material shall notify the Ministry of Health and the National Agency for Medicines and Medical Devices, as required, on all sponsoring activities as well as on any other expenses covered for physicians, nurses, professional organisations, patient organisations and any other types of organisations in the healthcare system, in accordance with provisions of the Order of the Minister of Health."

47. Under Article I, a new point, 131^1, is introduced after point 131, which reads as follows:

"131^1. Under Article 836 paragraph (1), points c), f), g), h), i), j) and m) are amended as follows:

«c) 5,000 RON to 10,000 RON penalty shall be applied to wholesale manufacturer/importer/distributor, as appropriate, in case of: conduct, within their premises, of activities other than authorised; distribution of medicinal

products from the manufacturer or wholesale distributors to units not authorised UNDER the law; distribution to drugstores of medicinal products other than released without medical prescription, participation of staff not appropriately qualified in technical operations requiring specialised training, in the manufacturing and distribution process, as well as violation of provisions on medicinal product labelling and package leaflet, reporting of changes in manufacturing/import or distribution, infringement of good practice in pharmacovigilance activity carried out by the marketing authorisation holder, non-compliance with storage conditions, non-compliance with legislation on export, subsidies and provision of medicinal product samples;

.....

f) 5,000 RON to 10,000 RON penalty shall be applied for absence of the chief pharmacist or their alternate from the distribution site premises during unit operation time; the same penalty applies for absence of the quality responsible person or their alternate from wholesale distribution site during working hours;

g) 10,000 RON to 30,000 RON penalty and one year suspension of the operation authorisation for manufacturers/importers/distribution units shall be applied in case one of the violations referred to under c), e), j) and m) is repeated within 3 months.

h) 5,000 RON to 20,000 RON penalty and suspension of wholesale distribution authorisation, in case of non-compliance with the Guideline on Good Wholesale Distribution Practice, until remedy of the reported deficiencies; the same penalty and exclusion from the registry of brokers apply for brokers not compliant with specific provisions of the Guideline for Good Wholesale Distribution Practice;

i) 10,000 RON to 30,000 RON penalty, for marketing authorisation holders' failure to:

- comply with conditions/restrictions included in the marketing authorisation, related to medicinal product release/use, as well as with those concerning medicinal product safe and effective use;

- report adverse reactions to the National Agency for Medicines and Medical Devices, do not submit Periodic Safety Update Reports to the National Agency for Medicines and Medical Devices,

- submit changes (variations) to marketing authorisation terms,

- notify the National Agency for Medicines and Medical Devices on the date of actual marketing,

- provide the Ministry of Health or, as required, the National Agency for Medicines and Medical Devices, data on the volume of sales and prescriptions of the medicinal product, in accordance with the provisions of this title;

j) 2,000 to 5,000 RON penalty shall be applied for importers' failure to report the status of each import to the National Agency for Medicines and Medical Devices, in accordance with legislation in force, or if the respective reporting is inaccurate or incomplete;

.....

m) 10,000 RON to 30,000 RON penalty shall be applied for manufacturers'/ importers'/wholesale distributors' failure to report to the National Agency for Medicines and Medical Devices, in accordance with the legislation in force, the status of each medicinal product supplied or if the respective reporting is inaccurate or incomplete;

48. Under Article I point 132, point m^1) of paragraph (1) of Article 836 is amended as follows:

"m^1) 50,000 to 100,000 RON penalty, for non-compliance with requirements mentioned under Article 695 (17) and Article 792 (2), as well as with requirements established in accordance with Article 787 (6)."

49. Under Article I, a new point, 132^1, is introduced after point 132, which reads as follows:

"132^1. Under Article 836 paragraph (1), a new point, m^2), is introduced after point m^1), which reads as follows:

«m^2) 50,000 to 100,000 RON penalty, for non-compliance of the marketing authorisation holders or their representatives with requirements mentioned under Article 695 (17) and Article 792 (2), as well as with requirements established in accordance with Article 787 (6)."

50. Under Article I, a new point, 133^1, is introduced after point 133, which reads as follows:

"133^1. Under Article 836 paragraph (1), two new points, x) and y), are introduced after point v), which read as follows:

«x) 5,000 to 10,000 RON penalty, for non-compliance with Article 787 (4) of distributors other than marketing authorisation holders."

y) 5,000 to 10,000 RON penalty, for manufacturer's/importer's/wholesale distributor's/retail distributor's/ marketing authorisation holder's non-compliance, as required, with provisions related to medicinal product advertisement."

51. Under Article I point 136, a new point, f), is introduced after point e) of paragraph (1) of Article 868, which reads as follows:

"f) provision of information to patients related to items with mandatory inclusion in medical prescription issued in Romania, released in a different Member State."

52. Under Article I point 136 Title XVIII "Cross-border medical assistance", Chapter III, Article 870, paragraph (2) is amended as follows:

"(2) The Ministry of Health publishes on its website the information mentioned under (1), in accordance with norms approved through joint Order of the Minister of Health and of the President of the National Health Insurance House."

53. Under Article I point 136, paragraph (3) of Article 887 is amended as follows:

"(3) In line with this Title, a specialised structure is the Medical Devices Department of the National Agency for Medicines and Medical Devices, with specific assignments in the field of medical devices."

54. Under Article I point 136, paragraphs (1) and (3) of Article 888 are amended as follows:

"ARTICLE 888

(1) Activities related to the marketing, distribution and supply of services in the field of medical devices are performed in accordance with provisions of this Title and of implementation rules, approved through Order of the Minister of Health.

.....

(3) The approval mentioned under (2) is granted by the National Agency for Medicines and Medical Devices, in accordance with applicable implementation rules, based on assessment of the expertise and ability of natural or legal persons, as required, to perform activities requiring approval. "

55. Under Article I point 136, Articles 890 - 895, 898 - 901 and 903 are amended as follows:

"ARTICLE 890

Commissioned and in-use medical devices shall comply, according to the terms established through instructions approved through Order of the Minister of Health, with the following types of control:

a) periodic check-up;

b) unannounced inspection and testing;

c) in-use surveillance.

ARTICLE 891

Assessment activities mentioned under Article 888 (3) and control activities stipulated under Article 890 are performed by the National Agency for Medicines and Medical Devices.

ARTICLE 892

(1) In line with provisions of this Title, the National Agency for Medicines and Medical Devices has the following main duties:

a) to elaborate specific technical procedures for medical devices;

b) to assess and/or audit, upon request, natural or legal entities applying for approval as mentioned under Article 888 (3);

c) to ensure, by examination and testing, control of medical devices in use, in accordance with implementation norms approved through Order of the Minister of Health;

d) to ensure assessment of the performance of medical devices, under conditions mentioned in this Title;

e) periodically inform the Ministry of Health about activities conducted in the respective field of competence.

(2) The National Agency for Medicines and Medical Devices performs other activities as well, in accordance with the law.

ARTICLE 893

(1) Second-hand medical devices, provided free of charge or purchased, shall only be marketed, commissioned and used after assessment by the

National Agency for Medicines and Medical Devices and based on grant of approval.

(2) Second-hand medical devices mentioned under (1), marketed and/or commissioned, must be labelled with the EC marking, on condition of assessment of compliance prior to placement on the market, in accordance with European rules on medical devices.

ARTICLE 894

(1) The National Agency for Medicines and Medical Devices is the competent, decision-making authority for medical devices.

(2) The National Agency for Medicines and Medical Devices performs the duties of a competent authority, as mentioned in the legislation, and proposes the Minister of Health regulatory acts for transposition of European directives or implementation of the legal framework of EU regulations in the field of medical devices, as required.

(3) The policy related to medical devices is established by the Ministry of Health.

(4) The Commission for Medical Devices and the Medical Devices Department of the National Agency for Medicines and Medical Devices organise clinical investigation of medical devices on human subjects, in accordance with provisions of regulations in force.

(5) The constituents, organisation and assignments of the Commission for Medical Devices are approved through Order of the Minister of Health.

ARTICLE 895

(1) To ensure appropriate safety and performance suitable to the intended purpose of the medical device and to avoid incidents, users are required:

a) to use medical devices for their intended purpose only;

b) to ascertain that medical devices are used during their period of validity only, when required, and that no deviations exist from operational performance and applicable safety requirements;

c) to enforce a programme for surveillance of medical devices, taking into account the risk posed to the patient, their intended use and complexity, in accordance with implementation rules in force;

d) to ensure periodic check-up, maintenance and repair of medical devices in collaboration with facilities specialised in delivery of such services;

e) to notify manufacturers and the specialised structure about any incident during use;

f) to report to the National Agency for Medicines and Medical Devices all medical devices in the unit, recorded as fixed assets in the accounting records, irrespective of their manner of acquisition, in accordance with the implementation rules approved through Order of the Minister of Health;

g) to ensure a documented inventory system for medical devices in use, repaired and checked, in accordance with implementation rules in force.

(2) medical devices in use for clinical investigation or assessment of performance for certification purposes, compliant with regulations or, as

required, with the procedure for assessment of compliance stipulated in the applicable technical regulation are exempt from provisions of par. (1).

(3) Users of medical devices shall ensure spare parts for used and commissioned medical devices as well as units able to perform the respective servicing.

.....

ARTICLE 898

(1) The offence notice and application of civil penalties are performed by staff of the National Agency for Medicines and Medical Devices, assigned in this respect.

(2) The legal or natural entity may file a complaint against the offence notice, within 15 days after notification, to the courthouse in whose territorial area the offence has taken place.

(3) The court decision is subject to means of appeal as stipulated by the law.

(4) Decisions on civil liability mentioned in Title XIX are supplemented with those of Government Ordinance no. 2/2001 on the legal regime of civil liability, approved as amended through Law 180/2002, as amended.

ARTICLE 899

Data recorded in accordance with this Title are stored into a database organised and coordinated by the National Agency for Medicines and Medical Devices.

ARTICLE 900

The implementation rules and instructions approved through Order of the Minister of Health are published in accordance with provisions of this Title.

ARTICLE 901

As regards examinations mentioned under Article 892 (1) b) - d), the National Agency for Medicines and Medical Devices establishes and collects fees for fee-based services, as established through Order of the Minister of Health.

.....

ARTICLE 903

Within 3 months as of entry into force of this Title, the medical devices specialised structure within the National Agency for Medicines and Medical Devices shall issue implementation rules, as approved through Order of the Minister of Health."

56. Articles II - V shall be repealed.

57. Under Article VII, paragraphs (1), (5), (6) and (7) shall be repealed.

58. Under Article VII, paragraph (2) is amended as follows:

"(2) Provisions of Article 54 (1) and (4), Article 220 to 262^1 of Law no. 95/2006, as amended, as amended through this Emergency Ordinance, shall come into force on 1 January 2015. "

59. Articles VIII and X shall be repealed.

60. Under Article XII, point 1 shall be repealed.

61. Under Article XII, a new point, 3, is introduced after 2, which reads as follows:

"3. Article 4 is amended as follows:

«ARTICLE 4

By exemption, before nationwide completion of implementation of the centralised system for acquisition of medicinal products, health materials, medical equipment, protection equipment, services, fuel and lubricants for the auto park, the Ministry of Health may approve acquisitions performed by public health units.»"

62. Article XV shall be repealed.

ARTICLE II

Government Decisions mentioned under Article 872 (3) and (4), Article 873 (1) d) and (5), Article 874 (3) b) and (4), Article 876 (1) a) (i) and (2), Article 877 (1) and Article 880 (2) and (4) of Law 95/2006 on healthcare reform, as amended, including those incurred by this Law, shall be set up in 30 days as of publication of this Law in the Official Gazette of Romania, Part I.

This Law has been adopted by the Romanian Parliament, in accordance with Article 77 (2), in line with provisions of Article 75 and Article 76 (2) of the Romanian Constitution, republished.

On behalf of the PRESIDENT OF THE CHAMBER OF DEPUTIES,
VIOREL HREBENCIUC

PRESIDENT OF THE SENATE,
CĂLIN-CONSTANTIN-ANTON POPESCU-TĂRICEANU

Bucharest, 9 October 2014.
No. 132.
