THE GOVERNMENT OF ROMANIA

EMERGENCY ORDINANCE
amending certain healthcare regulations

Having regard to Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use as regards the prevention of the entry into the legal supply chain of falsified medicinal products,

Taking into account Romania's obligation to observe deadlines for transposition of Directive 2011/62/EU into national law, namely by 31 December 2012,

To reduce the risk of action for failure to fulfil Member State obligations, according to art. 258 of the Treaty on the Functioning of the European Union,

Taking into account that transposition of the directives in question provide the necessary and obligatory conditions for achievement of quality medical intervention for citizens of Romania,

Having in mind that failure to meet these provisions entails the risk of decisions by the European Court of Justice imposing payment by Romania of financial penalties, according to art. 260(3) of the Treaty on the Functioning of the European Union, with major negative impact on the state budget,

Taking into account the Communication from the European Commission 2011/C 12/01 on Implementation of Article 260 (3) of the Treaty on the Functioning of the European Union, in particular the obligation of Member States to transpose directives within the deadlines laid down by the legislator and hence to ensure that Union legislation is genuinely effective,

Taking into account that failure to adopt emergency measures contained in this regulatory act may affect the rights of individuals, who may refer to national courts under the principle of the direct effect of directives, where harm has been done in result of non-compliance with European Union legislation on the prevention of the entry into the legal supply chain of falsified medicinal products,

Taking into account that the activities included in national health programs involve a mixture of interventions intended for the therapeutic structure for patients with chronic diseases, such as rare diseases, transplants of organs, tissues or cells, cancer, diabetes mellitus and others, which require high costs for a certain number of affected persons, also intended for the public health structure, and for medical services whose costs are not covered by the DRG system financed from the budget of the Single National Social Health Insurance Fund,

Taking into account the undertaking of the Romanian Government of the enforcement until 31 December 2012 of the measures meant for reorientation of national healthcare programs toward primary public health field in accordance with the "Health Action Plan",

For consistent regulation and adoption of immediate measures to ensure compliance with commitments of the Romanian Government in negotiations for loan agreements with financial institutions,

Taking into account that failure to adopt such immediate measures and as well as their implementing regulations, by emergency ordinance, would cause major disruptions adversely affecting the health of the population, as well as for efficient use of healthcare human and financial resources,

Considering that these factors of major impact on public health concern the general public interest and represent emergency and extraordinary situations whose regulation may not be delayed,

Pursuant to Article 115(4) of the Romanian Constitution, republished,

The Government of Romania hereby adopts this Emergency Ordinance.

Art. I. - Law 95/2006 on healthcare reform, published in the Official Gazette of Romania, Part I, No. 372 of 28 April 2006, as amended, is hereby amended as follows:

1. Under Article 6 h), after paragraph (8), two new points are introduced, points 9 and 10, as follows:

"9. Healthcare services for children;

10. Transfusion security services."

2. Under Article 6, a new point is introduced after point h), namely point i), which reads as follows:

"i) Medical and specific treatment of diseases with a major impact on public health (TB, HIV / AIDS, diseases, cancer, diabetes) and transplantation of organs, tissues or cells."

3. Under Article 8, paragraph c) is amended as follows:

"c) Activities within national health programs;".

4. Article 9 (3) and (5) are amended as follows:

"(3) National healthcare programs cover the main areas of intervention of public health and respond to national priorities identified by national health strategy.

.....

(5) National healthcare programs are developed by the Ministry of Health, with the participation of the National Health Insurance House; their development is carried out by the Ministry of Health and / or the National Health Insurance House as appropriate. "

5. Under Article 16 (1), points a) and c) are amended as follows:

"a) Establish national public health priorities, develop national healthcare programs and achieve coordination, monitoring, evaluation and control of the Ministry of Healthcare programs funded from the state budget and own revenues;

.....

c) Periodically assess the population's health indicators;".

6. Under Article 17 (2), point o) is amended as follows:

"o) Ensure the implementation of national healthcare programs run by their own structures, coordination, monitoring and enforcement of national public healthcare programs carried out under contracts with public institutions, healthcare providers network of local authorities, ministries and private health network institutions as well as private healthcare providers, as provided in the rules for performance of national public healthcare programs; ".

7. Under Article 17, paragraph (2^1) is repealed.

8. Article 45 is amended as follows:

"Art. 45. - (1) For the purposes of this title, the terms and expressions below have the following meanings:

a) National healthcare programs - overall annual action oriented toward the main areas of public healthcare intervention;

b) Development of national healthcare programs - the implementation, coordination, monitoring, evaluation and control of national healthcare programs;

c) the implementation of national healthcare programs, the organisation of human, material and financial resources at the level of special units in order to ensure the goods, services or changes of behaviours and of living and working environment for the beneficiaries of these programs in response to certain health needs identified in objective data;

d) Specialised unit - structure of the public health system assigned to the enforcement of national healthcare programs;

e) National/regional unit for technical assistance and management of national healthcare programs – the non-legal organisational structure of public institutions subordinated to the Ministry of Health, established by Order of the Minister of Health, responsible for providing technical assistance and management of national healthcare programs;

f) Technical assistance - all activities related to the training and information of special units responsible for the implementation of national healthcare programs and other activities undertaken to improve implementation of national healthcare programs;

g) Eligible expenditure - expenditure of goods and services carried out by specialised units assigned to the implementation of national healthcare programs, according to technical norms to achieve national healthcare programs.

(2) National healthcare programs address public health intervention areas as follows:

a) National public healthcare programs, which aim to ensure:

(i) The prevention, surveillance and control of communicable and non-communicable diseases;

(ii) Monitoring the health of the population;

(iii) Promote health and a healthy lifestyle;

(iv) Monitoring determinant factors of the living and working environment;

(v) The provision of specific public health services;

(vi) The provision of specific treatment for TBC and HIV / AIDS;

(vii) Implementation of transplantation procedures for organs, tissues or cells;

b) National curative healthcare programs ensuring specific treatment for diseases with a major impact on public health, other than TBC and HIV / AIDS and transplantation of organs, tissues and cells."

9. In Article 48, paragraphs (1) and (2)-(4) are amended as follows:

"Article 48. - (1) National healthcare programs are developed by the Ministry of Health, with the participation of the National Health Insurance House, and their performance is done separately, as follows:

a) By the Ministry of Health for public healthcare programs;

b) By the National Health Insurance for national curative healthcare programs.

.....

(2) The structure of national healthcare programs, their objectives, and any other terms and conditions needed in view of enforcement and development are approved through Government decision on the proposal of the Ministry of Health.

(3) The technical standards to achieve national healthcare programs are approved as follows:

a) By the Minister of Health for public healthcare programs;

b) By Order of the President of the National Health Insurance House, with the approval of the Ministry of Health for national curative healthcare programs.

(4) In epidemiological risk, national public healthcare program beneficiaries, except transplant procedures for organs, tissues or cells are all Romanian citizens residing in the country, foreigners and stateless persons who have requested and obtained an extension of the right of temporary or permanent residence in Romania, as well as all citizens in transit through Romania."

10. Under Article 48, paragraphs (5) and (6) are repealed.

11. Article 49 is amended as follows:

"Article 49. - (1) The enforcement of national healthcare programs is carried out by specialised units selected based on criteria approved through the technical standards to perform national healthcare programs.

(2) For the purposes of this law, specialised units are:

a) Public institutions;

b) Public healthcare providers;

c) Private healthcare providers for medical services that exceed the capacity of public providers of medical services;

d) Private providers of medicinal products and medical devices.

(3) Specialised units under paragraph (2) may be employed to implement national healthcare programs as multiannual actions throughout the entire period of implementation, in accordance with relevant legal provisions.

(4) In order to perform the duties and activities included in national healthcare programs, specialised units mentioned under paragraph (2) may sign contracts for services with physicians, medical assistants and other staff, as appropriate, as well as with legal persons, in accordance with the provisions of Law No. 287/2009 on the Civil code, republished, as amended, and on the conditions established through the technical Norms for enforcement of national healthcare programs.

(5) The contracts for provision of services/temporary work contracts signed under the conditions laid down under paragraph (4) by the specialised units mentioned under paragraph (2) make provisions for multiannual actions, are civil and shall be available throughout the entire period of enforcement of national healthcare programs.

(6) The amounts necessary for the contracts referred to in paragraph (3) and (4) are included in the funds allocated to national healthcare programs. "

12. Article 49[1] is amended as follows:

"Art. 49[1]. - (1) The implementation of national healthcare programs is done from Ministry of Health budget appropriations from state budget and own revenues, as follows:

a) Public and healthcare providers under the Ministry of Health;

b) Healthcare providers network of local authorities and ministries and institutions with their own health network, public and private healthcare providers, observing Art. 49 paragraph (2) point c) under contract with public health departments or, where appropriate, public institutions subordinated to the Ministry of Health.

(2) The implementation of national curative healthcare programs is done with the amounts allocated from the budget of the Single National Social Health Insurance Fund through the assessed suppliers of medical services, medicinal products and medical devices, according to the contracts signed with health insurance houses."

13. Article 50 is amended as follows:

"Art. 50. - The responsibilities of Ministry of Health national healthcare programs are:

a) To approve the strategy of national healthcare programs, part of the national health strategy;

b) To propose to the Government for approval by national healthcare programs;

c) To approve the methodological norms for achieving national public healthcare programs;

d) To approval of the methodological norms to enforce the national healing programs developed by the National Health Insurance House;

e) To organise national procedures for public acquisitions in view of procuring goods and services needed to implement national healthcare programs, in compliance with legal provisions on public acquisition;

f) To organise, monitor, assess and control the enforcement of national public healthcare programs;

g) To finance national healthcare programs. "

14. Article 51 is amended as follows:

"Art. 51. – The responsibilities of the Ministry of Health structure concerning the development and coordination of national healthcare programs are:

a) To participate in the development strategy of national healthcare programs, which is integral part of the national health strategy;

b) To elaborate the structure of national healthcare programs in collaboration with specialised departments of the Ministry of Health and the National Health Insurance House;

c) To substantiate the required financial resources for the development of national healthcare programs according to the proposals of regional/national units for technical assistance and management of national healthcare programs and/or specialised departments of the Ministry of Health, as appropriate;

d) To propose to the Minister of Health technical standards for performance of national public healthcare programs, issued in cooperation with the specialised departments of the Ministry of Health, in view of approval;

e) To achieve the coordination, monitoring, assessment and control of the enforcement of national public healthcare programs directly or through regional/national units for technical assistance and management of national healthcare programs in cooperation with the specialised departments of the Ministry of Health;

f) To propose to the Minister of Health measures to improve the performance of national healthcare programs."

15. Article 52 is amended as follows:

"Art. 52. - The responsibilities of the National Health Insurance House, as far as national healthcare programs are concerned, are as follows:

a) To participate in preparing the draft Government Decision for approval of national healthcare programs;

b) To develop and approve the technical standards required in view of developing national curative healthcare programs, with the assent of the Ministry of Health;

c) To organise, monitor, assess and control the enforcement of national curative healthcare programs;

d) To provide the financing of national curative healthcare programs;

e) To forward to the structure responsible with the development and coordination of national healthcare programs, quarterly, annually and whenever necessary, curative indicators of national programs and analyse how they are implemented. "

16. Article 53 is amended as follows:

"Art. 53. - (1) The Ministry of Health designates subordinated public institutions to provide technical assistance and management of national healthcare programs and establish technical and management units of national healthcare programs within the institutions designated through Order of the Minister of Health.

(2) Units of technical assistance and management of national healthcare programs may be set up at national or regional level as appropriate.

(3) A single unit for technical assistance and management of national healthcare programs which can ensure technical assistance and management of one or several national healthcare programs shall be set up within a public institution subordinated to the Ministry of Health, as appropriate.

(4) The organisational structure of technical and management units of national healthcare programs, their duties and any other necessary condition in view of operation shall be approved through the technical standards to achieve national healthcare programs.

(5) Expenses for organisation and operation of technical and management units of national healthcare programs are included in the amounts allocated to the national healthcare programs they manage, these being settled in accordance with the complexity of the activity performed, with the approval of the Ministry of Health.

(6) To achieve technical and management functions of national healthcare programs, public institutions under paragraph (1) may employ personnel without exceeding the maximum number of positions approved by the Ministry of Health and its subordinate institutions, and / or may contract for the provision of services / civil agreement according to Art. 49 paragraph (3) - (6), in accordance with the legal provisions in force. "

17. Article 54 is amended as follows:

"Art. 54. - (1) The financing of national healthcare programs is done as follows:

a) From the Ministry of Health budget, the state budget and from its own revenues issued from national curative healthcare programs;

b) From the unique National Fund for health insurance for curative healthcare programs;

c) From other sources, including donations and sponsorships, in accordance with the law;

(2) The amounts allocated to multiannual national healthcare programs are approved through state budget law in accordance with the provisions of Law 500/2002 on public finances, as amended.

(3) In case of national public healthcare programs, categories of eligible expenditure and the financing thereof shall be approved by the technical standards to achieve national healthcare programs.

(4) In case of national curative healthcare programs, the medicinal products, healthcare materials, medical devices and such, released through open circuit

pharmacies, granted to the beneficiaries included in national curative programs are supported from the budget of the Single National Social Health Insurance Fund at discount price.

(5) Medicinal products, medical supplies, medical devices and the like, used in medical facilities with beds to treat patients during their hospitalisation or, where applicable, issued by closed circuit pharmacies for outpatient treatment of patients enrolled in national healthcare programs are covered in the purchase price for medicinal products which cannot exceed the settlement price.

(6) The purchase of medicines, medical equipment, medical devices and such specified in paragraph (5) is done by public acquisition procedures organised by the Ministry of Health or by health facilities with beds that implement national healthcare programs, as appropriate, in accordance with the legal provisions on public acquisitions.

(7) The List of medicinal products covered within national healthcare programs is approved by Government Decision."

18. Article 55 is amended as follows:

"Article 55. - (1) The amounts allocated for healthcare programs are included in the revenue and expenditure of the specialised units in which they are implemented.

(2) The amounts referred to in paragraph (1) shall be posted on the website of the Ministry of Health.

(3) "Specialised Units" published on its website the income and expenditure and implementation of the budget of revenues and expenditures for healthcare programs. "

19. Article 56 is amended as follows:

"Art. 56. - Specialised units that enforce national healthcare programs must use the granted funds within budget and according to the destination specified by the legal provisions and the obligation to efficiently manage material and financial resources and accounting organisation expenses for each program, the budget classification subdivisions, the approved budget and the implementation of the budget of income and expenses. "

20. Article 57 is amended as follows:

"Article 57. - (1) The Ministry of Health provides funds for financing national healthcare programs at the request of technical assistance and management units of national healthcare programs.

(2) The National Health Insurance House provides the funds required for the financing of national curative programs at the request of health insurance houses.

(3) Requests for financing national healthcare programs provided in paragraphs (1) and (2) are made using specialised unit based applications that will require funding depending on the achievement indicators and within the limits of the funds approved for this purpose."

21. Under Article 80, point d) is amended as follows:

"d) Contracts with local public health authorities or public institutions under the Ministry of Health in view of implementing national public healthcare programs."

22. Under Article 81[1], paragraph (1) is amended as follows:

"Art. 81[1]. - (1) The state budget, via the Ministry of Health budget, can finance infrastructure investments in rural areas for construction, rehabilitation, minimum standard endowment of medical and non-medical areas where primary healthcare activities are conducted."

23. A new article is introduced after Article 92, Article 92[1], which reads as follows:

"Art. 92[1]. - (1) The medical assistant, the emergency registry operator and the controller/radio telephone operator, as well as the driver of ambulance continually perform various activities in the context of the activity performed by ambulance services, namely emergency pre-hospital medical assistance and assisted medical transportation.

(2) The activity performed by the medical assistant, the emergency registry operator and the controller/radio telephone operator, as well as by the driver of the ambulance from ambulance services, to ensure continuity in emergency medical care, outside the regular schedule, assimilates with the activity of guarding medical staff and benefits from the rights mentioned in Chapter II Art. 3 of Annex III of Framework Law No. 284/2010 on the unitary remuneration of staff paid from public funds, as amended, if there is not enough spare time granted in accordance with the type activity performed beyond regular working hours."

24. Under Article 93, paragraph (1) is amended as follows:

"Art. 93. - (1) The financing for grant of emergency public medical assistance is done via the Ministry of Health from state budget and personal revenues, via the budget of the Ministry of Administration and Internal Affairs, of ministries and institutions with personal healthcare network, from donations and sponsorships, as well as from other sources, as provided by law."

25. Under Article 93, paragraph (11) is amended as follows:

"(1[1]) The financing of county ambulance services, namely of the Bucharest-Ilfov Ambulance Service is provided from the state budget through the Ministry of Health. Criteria for allocation of funds are approved through Order of the Minister of Health."

26. Under Article 93, a new paragraph is introduced after paragraph (1[1]), paragraph (2[1]), which reads as follows:

"(1[2]) Emergency consultations at home and unattended medical transport can also be achieved by private providers through direct contractual relationship with the Health Insurance House, coordinated by public ambulance services."

27. Under Article 93, paragraph (3) is repealed.

28. Under Article 93, paragraph (4) is amended as follows:

"(4) Funds from emergency regional hospitals and grade II emergency county hospitals, meant for dealing with critical cases whose expenditures cannot

be covered from funds obtained from contracts with health insurance houses are granted from Ministry of Health budget, state budget and personal revenues.”

29. Under Article 93, a new paragraph is introduced after paragraph (4), paragraph (4^1), which reads as follows:

"(4^1) The list of hospitals and their sections, the description of the expenditures, the manner of distribution of the funds provided in paragraph (4), as well as any other terms and conditions shall be established through Order of the Minister of Health."

30. Under Article 93, paragraph (5) is amended as follows:

"(5) The emergency units and departments from emergency hospitals are financed from state budget and from Ministry of Health revenues, from the state budget through the budgets of ministries and institutions with their own healthcare network covering staff expenditures, medicinal products, reagents and medical supplies, costs for laboratory investigations performed in these structures, without requiring their admission in the healthcare unit which includes the respective emergency reception unit / emergency reception centre".

31. Under Article 107, paragraph (2) is amended as follows:

"(2) The department of emergency medical assistance works in a standby regime."

32. Under Article 110, paragraphs (1) and (2) are repealed.

33. Under Article 182, paragraph (1^1) is amended as follows:

"(1^1) The Manager shall negotiate and conclude contracts for supply of medical services with the health insurance house as well as with the public health department or, where appropriate, with public institutions subordinated to the Ministry of Health to enforce national public healthcare programs and insurance costs referred to in Art. 190^1.”

34. Under Article 184, paragraph (2) is amended as follows:

"(2) In public hospitals, jobs such as head of service, head of laboratory, chief medical assistant represent management positions and can only be occupied by physicians, biologists, chemists and biochemists or, where appropriate, by medical assistants, having at least 5 years of experience in the given field."

35. Under Article 184, a new paragraph is introduced after paragraph (2), paragraph (2^1), which reads as follows:

"(2^1) The job of head pharmacist in public hospitals can be occupied, in accordance with the law, by pharmacists having at least 2 years of professional experience."

36. Under Article 189, paragraph (4) is amended as follows:

"(4) Public hospitals may sign contracts for the implementation of national curative healthcare programs with health insurance houses, as well as with county public healthcare departments and public healthcare departments in Bucharest or, where appropriate, with public institutions subordinated to the Ministry of Health to implement national public healthcare programs according to their organisational structure. "

37. Under Article 189[1], paragraph (1) is amended as follows:

"Art. 189[1]. - (1) Income derived by public health units in line with healthcare contracts concluded with health insurance funds cannot be used for:

a) Investments in infrastructure;

b) Provision of medical equipment worth more than 15,000 euro without VAT / medical equipment.

38. Under Article 190 paragraph (2), points a), b) and f) are amended as follows:

"a) Implementing national healthcare programs;

b) The purchase of medical equipment and other facilities independent of the nature of capital expenditure, in accordance with the law;

.....

f) Specific activities of ministries and institutions having their own healthcare network, approved by Government Decision; ".

39. Under Article 190 paragraph (3), point b) is amended as follows:

"b) Funds from the state budget and from personal revenues shall be granted for the enforcement of national public health programs through Ministry of Health budget, in line with the contracts signed with the Public Health Department of Bucharest or with other public institutions subordinated to the Ministry of Health, as required;".

40. Under Article 190[1], point a) is amended as follows:

"a) The enforcement of national public health programs;".

41. Article 196[1] is amended as follows:

"Art. 196[1]. - (1) Medical assistants employed in the public system on account of their diploma/certificate obtained from specialised short-term upper/postgraduate medical studies, who graduated from related higher education, fall under the category of the adequate status of graduated higher education, while maintaining their "senior" degree and the status they had on the date of their graduation.

(2) Medical assistants employed in the public system on account of their diploma/certificate obtained from specialised short-term upper/postgraduate medical studies, who graduated from related higher education and have subsequently obtained the "senior" degree according to the graduated higher education benefit from the "senior medical assistant" status corresponding to their graduated higher education, while maintaining the status they had on the date of their graduation."

42. Under Article 210 paragraph (1), points e), k) and l) are amended as follows:

"e) Minimum package of services - is granted to persons who are not insured and includes medical services only in case of medical-surgical emergencies and potentially endemoepidemic diseases; it also includes the monitoring of the progress of pregnancy and breastfeeding, family planning, established through framework contract;

.....

k) Reimbursement price - the price granted from the Single National Social Health Insurance Fund for medicines, medical equipment, medical devices and such issued through open circuit pharmacies for ensured employees included in national curative healthcare programs. Their list and the reimbursement price are approved through Order of the Minister of Health;

l) Co-payment - the amount representing payment of the money to the ensured employees in line with the provisions of Art. 219 g) in order to receive medical services included in the basic package of services, in the context of the social health insurance system, according to the proportion and under the conditions established through framework contract concerning the granting of medical assistance in the context of the social health insurance system, according to the provisions of Art. 217 (3) k) ".

43. Under Article 213^{2}, paragraph (5) is amended as follows:

"(5) Co-payment revenues represent incomes of healthcare providers and are used to improve service quality."

44. Under Article 217, paragraph (4) is amended as follows:

"(4) Where the law of the state budget is not approved until 31 December of the current year, the time limits in paragraph (2) and (5) are extended until February 28 next year.'

45. Article 220 is amended as follows:

"Article 220. - People who cannot prove their insurant status only have access to healthcare services in case of surgical emergencies and endemic-epidemic diseases; they also have access to the monitoring of pregnancy, nursing and family planning services in line with the provisions of Art. 223 within a minimum package of healthcare services established by framework contract. "

46. Under Article 223 (2), point d) is repealed.

47. Under Article 233, paragraphs (6) and (7) are repealed.

48. Article 235 is amended as follows:

"Article 235. - Insurants are entitled to medical transport, required in view of receiving healthcare services in the following situations:

a) Surgical emergencies;

b) Cases specified in the framework contract. "

49. Article 241 is amended as follows:

"Article 241. - In order to accomplish the objectives of the National health strategy, the Ministry of Health develops national healthcare programs in collaboration with the National Health Insurance House."

50. Article 242 is amended as follows:

"Art. 242. - Outpatient medicinal products that are granted in the context of national curative healthcare programs are ensured through pharmacies belonging to healthcare units which enable this performance or through other pharmacies, as

required."

51. Under Article 244, paragraph (2) is amended as follows:

"(2) The evaluation process includes medical offices, ambulatory care units, hospitals, pharmacies, home care providers, medical device providers, private providers of emergency consultations at home and unattended medical transport, and other natural or legal persons authorized in this respect by the Ministry of Health."

52. Article 252 (1), subparagraphs e) and g) are amended as follows:

"e) Settlement price for medicinal products, medical equipment, medical devices and the like, obtained by open circuit pharmacies for insured enrolled in curative healthcare programs;

.....

g) The purchase price of medicinal products, medical equipment, medical devices and the like used in medical facilities with beds for treatment of patients during their hospitalisation or, where applicable, issued by closed circuit pharmacies for outpatient treatment of patients enrolled in national curative healthcare programs; ".

53. Article 255 is amended as follows:

"Article 255. – Emergency home consultations and unattended medical transportation provided by private providers is given by authorised and assessed specialised medical units."

54. Under Article 270 (1), point o) is amended as follows:

"o) To conclude and conduct supply contracts for dialysis medical services;".

55. Under Article 281 (1), point h) is amended as follows:

"h) Quarterly and annually submit to the Ministry of Health, as well as in the context of functional analyses, the activities performed by the National Health Insurance House related to medical services, medical devices provided to the insured, as well as to those insured included in national curative healthcare programs, their contracting, reimbursement and financing within the social health insurance system, as well as budget execution."

56. Article 322 is amended as follows:

"Article 322. – The European card is issued only if the insured travels for temporary stay in a Member State of the European Union. Under exceptional circumstances, which disable the use of the card by the insured, the health insurance house issues a provisional certificate which replaces the European card. The European card and its replacement entitle the holder to the same medical services. "

57. Article 362 is amended as follows:

"Art. 362. – The incomes referred to in Art. 361, managed by the Ministry of Health, are used to:

a) Investments in infrastructure and equipment of healthcare units included in the Ministry of Health network and of public hospitals included in the network of the local public administration authority, as provided in Art. 190^5 (1);

b) Financing national healthcare programs;

c) The reserve of the Ministry of Health for special situations;

d) Amounts allocated through transfer to the budget of the Single National Social Health Insurance Fund for medical services or medicinal products from which insured undergoing in-patient treatment benefit, with or without personal contribution, based on medical prescription, within the social health insurance system, and in view of settlement of payment obligations recorded in the end of 2012 limited to commitment appropriations approved for national healthcare programs;

e) Other destinations referred to in Art. 93 (11), Art. 93 (4), (5) and (5^1)."

58. Under Article 370, a new paragraph is introduced after paragraph (1), paragraph (2), which reads as follows:

"(2) Notwithstanding the provisions of Art. 371 paragraph (1), paragraph (3) d) and Art. 372, physicians who are citizens of a third state may perform occasional professional activities for educational purposes in Romania, with the approval of the Ministry of Health and of the Romanian College of Physicians. In this case, such activities can be performed no more than 3 months with possibility of extension for a further period of 3 months per year. The notification methodology approved by Order of the Minister of Health and with the approval of the Romanian College of Physicians, and is published in the Official Gazette of Romania, Part I."

59. Under Article 385, paragraphs (2) and (5) are amended and shall read as follows:

"(2) Upon request, physicians may retire under the terms of Law No. 263/2010 on the unitary system of public pensions, as amended.

.....

(5) In case of public healthcare units dealing with a lack of medical staff, as well as public healthcare units located in disadvantaged areas, physicians may continue their activity after having reached the age of retirement stipulated by law, at the proposal of the public healthcare unit, with the annual approval of the Romanian College of Physicians and of local county colleges in Bucharest and with the approval of the main credit ordinator, until the jobs are filled through examination."

60. Under Article 692, paragraphs (2) and (3) are amended as follows:

"(2) The SNSPMPDSB can carry out activities related to analysis, evaluation and monitoring of healthcare services reimbursed from the Single National Social Health Insurance Fund.

(3) The activities referred to in paragraph (2) are achieved through direct contract-based negotiations with the National Health Insurance House. "

61. Under Article 695, two new points are introduced after point 2, points 2^1 and 2^2, which read as follows:

"2^1. Active substance - any substance or mixture of substances intended to be used in the manufacture of a medicinal product which, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;

2^2. Excipient - any constituent of a medicinal product other than the active substance and the packaging material".

62. Under Article 695, a new point is introduced after point 16, point 16^1, which reads as follows:

"16^1. Brokering of medicinal products - all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;"

63. Under Article 695, a new point is introduced after point 36, point 37, which reads as follows:

"37. Falsified medicinal product - any medicinal product with a false representation of:

a) Its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

b) Its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder;

c) Its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights."

64. Under Article 696, paragraph (3) is amended as follows:

"(3) Notwithstanding paragraph 1 of this Article and of point d) in Article 697, Chapter IV of this Title shall apply to the manufacture of medicinal products intended only for export and to intermediate products, active substances and excipients."

65. Under Article 696, a new paragraph is introduced after paragraph (3), paragraph (4), which reads as follows:

"(4) Provisions of paragraph (1) shall apply without prejudice to Articles 761^2 and 796^1."

66. Under Article 699, paragraph (2) is amended as follows:

"(2) The National Agency for Medicines and Medical Devices may temporarily authorise the distribution of an unauthorised medicinal product in the event of a suspected epidemic or of a concerned epidemic with pathogens, toxins, as well as in the event of a (confirmed) suspected outbreak with chemical agents or nuclear radiations which could endanger public health or in other cases of need

uncovered by authorised products, under the conditions established through Order of the Minister of Health."

67. Under Article 702 (4), a new point is introduced after point i), point i^1), which reads as follows:

"i^1) A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with principles and guidelines of Good Manufacturing Practice by conducting audits, in accordance with point f) of Article 754. The written confirmation shall contain a reference to the date of the audit and a declaration according to which the outcome of the audit confirms manufacturing compliance with GMP principles and guidelines."

68. Under Article 748, paragraph (4) is amended as follows:

"(4) The National Agency for Medicines and Medical Devices shall enter the information relating to the authorisation referred to in paragraph (1) into the European Union database referred to in Article 823 (6)."

69. Under Article 754, point f) is amended as follows:

"f) To comply with the principles and guidelines of Good Manufacturing Practice for medicinal products and to use only active substances, which have been manufactured in accordance with Good Manufacturing Practice for active substances and distributed in accordance with Good Distribution Practices for active substances. To this end, the holder of the manufacturing authorisation shall verify compliance by the manufacturer and distributors of active substances with Good Manufacturing Practice and Good Distribution Practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. The holder of the manufacturing authorisation shall verify such compliance either by himself or, without prejudice to his responsibility as provided for in this Law, through an entity acting on his behalf under a contract. The holder of the manufacturing authorisation shall ensure that the excipients are suitable for use in medicinal products by ascertaining what the appropriate Good Manufacturing Practice is. This shall be ascertained on the basis of a formalised risk assessment in accordance with the applicable guidelines referred to in point d) of Article 756. Such risk assessment shall take into account requirements under other appropriate quality systems as well as the source and intended use of the excipients and previous instances of quality defects. The holder of the manufacturing authorisation shall ensure that the appropriate Good Manufacturing Practice so ascertained, is applied. The holder of the manufacturing authorisation shall document the measures taken under this point;"

70. Under Article 754, three new points are introduced after point f), which read as follows:

"g) To immediately inform the National Agency for Medicines and Medical Devices and the marketing authorisation holder if he/she obtains information that medicinal products which come under the scope of his/her manufacturing authorisation are, or are suspected of being, falsified irrespective of whether those

medicinal products were distributed within the legal supply chain or by illegal means, including illegal sale by means of information society services;

h) To verify that the manufacturers, importers or distributors from whom he obtains active substances are registered with the competent authority of the Member State in which they are established;

i) To verify the authenticity and quality of the active substances and the excipients."

71. A new Article is introduced after Article 755, Article 755[1], which reads as follows:

"Art. 755[1]. - (1) The National Agency for Medicines and Medical Devices shall take appropriate measures to ensure that the manufacture, import and distribution on their territory of active substances, including active substances that are intended for export, comply with Good Manufacturing Practice and Good Distribution Practices for active substances.

(2) Active substances shall only be imported if the following conditions are met:

a) The active substances have been manufactured in accordance with standards of Good Manufacturing Practice at least equivalent to those laid down by the European Union pursuant to point b) of Article 756;

b) The active substances are accompanied by a written confirmation from the competent authority of the exporting third country of the following:

(i) The standards of Good Manufacturing Practice applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the European Union pursuant to point b) of Article 756;

(ii) The manufacturing plant concerned is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure public health protection at least equivalent to that in the European Union;

(iii) In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country to the European Union without any delay. This written confirmation shall be without prejudice to the obligations set out in Article 702 and point f) of Article 754.

(3) The requirement set out in point b) of paragraph (2) shall not apply if the exporting country is included in the list referred to in Article 823[2].

(4) Exceptionally and where necessary to ensure the availability of medicinal products, when a plant manufacturing an active substance for export has been inspected by a Member State and was found to comply with the principles and guidelines of Good Manufacturing Practice laid down pursuant to point b) of Article 756, the Ministry of Health and the National Agency for Medicines and Medical Devices may waive the requirement set out in point b) of paragraph (2) for a period not exceeding the validity of the GMP certificate; the Ministry of Health and the National Agency for Medicines and Medical Devices

shall inform the European Commission when use is made of the possibility of such waiver. “

72. Article 756 is amended as follows:

"Art. 756. - The National Agency for Medicines and Medical Devices pursues application of:

a) The principles and guidelines of Good Manufacturing Practice for medicinal products for human use, as adopted by the European Commission;

b) The principles and guidelines of Good Manufacturing Practice for active substances referred to under point f) of Article 754 and Article 755^{1}, as adopted by the European Commission;

c) The principles of Good Distribution Practice for active substances referred to in point f) of Article 754, adopted by the European Commission in the form of guidelines;

d) The guidelines on the formalised risk assessment for ascertaining the appropriate Good Manufacturing Practice for excipients referred to in point f) of Article 754, as adopted by the European Commission.”

73. A new Article is introduced after Article 756, Article 756^{1}, which reads as follows:

"Art. 756^{1}. - (1) “Article 756^{1}. - (1) The safety features referred to in point o) of Article 763 shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:

a) The manufacturing authorisation holder verifies, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with;

b) The manufacturing authorisation holder complies with point o) of Article 763 by replacing those safety features with safety features which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging as defined in point 23 of Article 695. Safety features shall be considered equivalent if they comply with the requirements set out in the delegated acts adopted by the European Commission pursuant to Article 763^{1} (2), and are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;

c) The replacement of the safety features is conducted in accordance with applicable Good Manufacturing Practice for medicinal products;

d) The replacement of the safety features is subject to supervision by the National Agency for Medicines and Medical Devices.

(2) Manufacturing authorisation holders, including those performing the activities referred to in paragraph (1), shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in Law No. 240/2004 concerning manufacturer liability for defective products, republished as amended.”

74. Under Article 760, paragraph (1) is amended as follows:

"Article 760. - (1) The National Agency for Medicines and Medical Devices shall take all steps required to ensure that, in the context of procedures provided for in Article 761 and without prejudice to the relationship with the manufacturing authorisation holder, the Qualified Person referred to in Article 757 shall be held liable for ensuring the following:

a) For medicinal products manufactured in Romania, that each medicinal product batch has been manufactured and verified compliant with laws in force in Romania as well as with marketing authorisation requirements;

b) For medicinal products from third countries, regardless of whether the medicinal product has been manufactured in the European Union, that each medicinal product batch has been subject to a thorough qualitative review in a Member State as well as to a quantitative review of at least all active substances and to any other tests or verifications required to ensure medicinal product quality according to the requirements provided in the marketing authorisation.

For medicinal products intended for marketing in the European Union, the Qualified Person referred to in Article 757 shall ensure that safety features referred to in point o) of Article 763 have been affixed on the packaging. Medicinal product batches that have been subject to such review in a Member State are exempt from verification if marketed in Romania, accompanied by control reports signed by the Qualified Person."

75. Two new Articles are introduced after Article 761, Articles 761^1 and 761^2, which read as follows:

"Art. 761^1. - (1) Importers, manufacturers and distributors of active substances established in Romania shall register their activity with the National Agency for Medicines and Medical Devices.

(2) The registration form shall include at least the following information:

a) Name or corporate name and permanent address;

b) The active substances which are to be imported, manufactured or distributed;

c) Particulars regarding the premises and the technical equipment for their activity.

(3) The persons referred to in paragraph (1) shall submit the registration form to the National Agency for Medicines and Medical Devices at least 60 days prior to the intended onset of their activity.

(4) Based on a risk assessment, the National Agency for Medicines and Medical Devices may decide to carry out an inspection. If the National Agency for Medicines and Medical Devices notifies the applicant within 60 days of the receipt of the registration form that an inspection will be carried out, the applicant's activity shall not begin before the National Agency for Medicines and Medical Devices has notified the applicant that he/she may commence the activity. If, within 60 days of the receipt of the registration form, the National

Agency for Medicines and Medical Devices has not notified the applicant that an inspection will be carried out, the applicant may commence the activity.

(5) The persons referred to in paragraph (1) shall communicate annually to the National Agency for Medicines and Medical Devices an inventory of the changes which have taken place as regards the information provided in the registration form; any changes that may have an impact on the quality or safety of the active substances that are manufactured, imported or distributed must be notified immediately.

(6) The National Agency for Medicines and Medical Devices enters the information provided, pursuant to paragraph (2), into the European Union database referred to in Article 823(6).

(7) This Article shall be without prejudice to Article 823.

Art. 761^2. - (1) Notwithstanding Article 696(1) and without prejudice to Chapter VII, the National Agency for Medicines and Medical Devices and the other competent authorities shall take the necessary measures in order to prevent medicinal products that are introduced into Romania, but are not intended to be placed on the Romanian market, from entering into circulation if there are sufficient grounds to suspect that those products are falsified.

(2) In order to meet the requirements of paragraph (1), the National Agency for Medicines and Medical Devices and the other competent authorities, as applicable, shall apply measures established in delegated acts adopted by the European Commission, supplementing paragraph (1) as regards the criteria to be considered and the verifications to be made when assessing the potential falsified character of medicinal products introduced into Romania but not intended to be placed on the Romanian market."

76. Under Article 763, a new point is introduced after point n), point o), which reads as follows:

"o) For medicinal products other than radiopharmaceuticals referred to in Article 763^1 (1), safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product, identify individual packs, as well as a device allowing verification of whether the outer packaging has been tampered with."

77. A new Article is introduced after Article 763, Article 763^1, which reads as follows:

"Art. 763^1. - (1) Medicinal products subject to prescription shall bear the safety features referred to in point o) of Article 763, unless they have been listed in accordance with the procedure pursuant to point b) of paragraph (3).

(2) Medicinal products not subject to prescription shall not bear the safety features referred to in point o) of Article 763, unless, by way of exception, they have been listed in accordance with the procedure pursuant to point b) of paragraph (3), after having been assessed to be at risk of falsification.

(3) The National Agency for Medicines and Medical Devices shall adopt and apply detailed rules for the safety features referred to in point o) of Article 763, in line with provisions of delegated acts adopted by the European Commission on measures supplementing point o) of Article 763. Such rules set out:

a) The characteristics and technical specifications of the unique identifier of the safety features referred to in point o) of Article 763 that enable the authenticity of medicinal products to be verified and individual packs to be identified;

b) The lists containing the medicinal products or product categories which, in the case of medicinal products subject to prescription, shall not bear the safety features, and in the case of medicinal products not subject to prescription, shall bear the safety features referred to in point o) of Article 763. Those lists shall be established considering the risk of and the risk arising from falsification relating to medicinal products or categories of medicinal products. To this end, at least the following criteria shall be applied:

(i) The price and sales volume of the medicinal product;

(ii) The number and frequency of previous cases of falsified medicinal products being reported within the European Union and in third countries and the evolution of the number and frequency of such cases to date;

(iii) The specific characteristics of the medicinal product concerned;

(iv) The severity of the conditions intended to be treated;

(v) Other potential risks to public health;

c) The procedures for the notification to the European Commission provided for in paragraph 4 and an expedited system for evaluating and deciding on such notification for the purpose of applying point b);

d) The modalities for the verification of the safety features referred to in point o) of Article 763 by the manufacturers, wholesalers, pharmacists and persons authorised or entitled to supply medicinal products to the public and by competent authorities. Those modalities shall allow the verification of the authenticity of each supplied pack of the medicinal products bearing the safety features referred to in point o) of Article 763 and the assessment of the extent of such verification. When establishing those modalities, the particular characteristics of the supply chains in Member States, and the need to ensure that the impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account;

e) Provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, enabling the verification of the authenticity and identification of medicinal products, as provided for in point o) of Article 763. The costs of the repositories system shall be borne by the manufacturing authorisation holders of medicinal products bearing the safety features.

(4) The National Agency for Medicines and Medical Devices shall notify the European Commission of non-prescription medicinal products which they judge to be at risk of falsification and may inform the European Commission of medicinal products which they deem not to be at risk according to the criteria set out in point b) of paragraph (2).

(5) For the purposes of reimbursement or pharmacovigilance, the National Agency for Medicines and Medical Devices may extend the scope of application of the unique identifier referred to in point o) of Article 763 to any medicinal product subject to prescription or, on request by the Ministry of Health, to any medicinal product subject to reimbursement. For the purposes of reimbursement, pharmacovigilance or pharmacoepidemiology, the National Agency for Medicines and Medical Devices and the Ministry of Health, as applicable, may use the information contained in the repositories system referred to in point e) of paragraph (2).

For the purposes of patient safety, the National Agency for Medicines and Medical Devices may extend the scope of application of the anti-tampering device referred to in point o) of Article 763 to any medicinal product."

78. Under Article 767, paragraph (1) is amended as follows:

"Art. 767. - (1) In compliance with Article 770, the National Agency for Medicines and Medical Devices shall require use of forms of medicinal product labelling allowing for indication of legal status of release to the patient, according to Chapter VI and identification and authenticity features pursuant to Article $763^{1}(5)$."

79. The title of Chapter VII "Medicinal product distribution" is amended as follows:

"Chapter VII - Wholesale distribution and brokering of medicinal products"

80. Under Article 787, paragraph (4) is amended as follows:

"(4) Any distributor, not being the marketing authorisation holder, who imports a medicinal product from another Member State, shall notify the marketing authorisation holder and the National Agency for Medicines and Medical Devices of his intention to import that product."

81. Under Article 787, a new paragraph is introduced after paragraph (4), paragraph (5), which reads as follows:

"(5) In the case of medicinal products which have been granted an authorisation through the centralised procedure, the distributor shall submit the notification in accordance with paragraph (4) to the marketing authorisation holder and the European Medicines Agency."

82. Under Article 788, paragraphs (1), (5) and (6) are amended and shall read as follows:

"Art. 788. - (1) The National Agency for Medicines and Medical Devices shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to owning an authorisation to engage in activity as

a wholesaler of medicinal products, stating the premise(s) located in Romania for which it is valid.

.....

(5) The National Agency for Medicines and Medical Devices shall enter the information relating to the authorisations referred to in paragraph (1) into the European Union database referred to in Article 823(6); at the request of the European Commission or any Member State, the National Agency for Medicines and Medical Devices shall provide all appropriate information concerning the individual authorisations which they have granted under paragraph (1).

(6) Checks on the persons authorised to engage in activity as a wholesaler in medicinal products, and the inspection of their premise(s), shall be carried out under the responsibility of the National Agency for Medicines and Medical Devices which has granted the authorisation for premise(s) located in Romania."

83. Under Article 791, a new point is introduced after point c), point c^1), which reads as follows:

"c^1) They must verify that the medicinal products received are not falsified, by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts referred to in Article 763^1(3);"

84. Under Article 791, point e) is amended as follows:

"e) They must keep records either in the form of purchase/sales invoices or on computer, or in any other form, for any transaction in medicinal products received, dispatched or brokered giving at least the following information: date, name of the medicinal product, manufacturer's name and country of origin, formulation, pharmaceutical form, active substances strength, package size, batch number and expiry date, quality certificate and test report, as applicable, quantity received, provided or brokered, name and address of the supplier or consignee, as appropriate, as well as batch number of the medicinal products at least for products bearing the safety features referred to in point o) of Article 763;"

85. Under Article 791, two new points, points h) and i), are inserted after point g), which shall read as follows:

"h) They must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities;

i) They must immediately inform the National Agency for Medicines and Medical Devices and, where applicable, the marketing authorisation holder, of medicinal products received or granted which they identify as falsified or suspect to be falsified.

For the purposes of point b), where the medicinal product is obtained from another wholesale distributor, wholesale distribution authorisation holders must verify compliance with the principles and guidelines of Good Distribution Practices by the supplying wholesale distributor; this includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation.

Where the medicinal product is obtained from the manufacturer or importer, wholesale distribution authorisation holders must verify that the manufacturer or importer holds a manufacturing authorisation.

Where the medicinal product is obtained through brokering, the wholesale distribution authorisation holders must verify that the broker involved meets the requirements set out in this regulatory document."

86. Under Article 793, paragraph (1) is amended as follows:

"Art. 793. - (1) For all supplies of medicinal products to a person authorised to supply medicinal products to the public in Romania, the authorised wholesaler must enclose a document that makes it possible to ascertain: the date, name and pharmaceutical form of the medicinal product, the quantity supplied, the name and address of the supplier and consignee as well as the batch number of the medicinal products at least for products bearing the safety features referred to in point (o) of Article 763."

87. Two new Articles are introduced after Article 796, Article 796^1 and 796^2, which read as follows:

"Art. 796^1. - Article 787 and point c) of Article 791 shall not apply in the case of wholesale distribution of medicinal products to third countries. Points b) and c^1) of Article 791 shall not apply where a product is directly received from a third country but not imported. The requirements set out in Article 793 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.

Art. 796^2. - (1) Persons brokering medicinal products shall ensure that the brokered medicinal products are covered by a marketing authorisation granted pursuant to the centralised procedure or by the National Agency for Medicines and Medical Devices in accordance with this law. Persons brokering medicinal products shall have a permanent address and contact details in Romania or a different Member State, so as to ensure accurate identification, location, communication and supervision of their activities by the National Agency for Medicines and Medical Devices or other competent authorities. The requirements set out in points d) to i) of Article 791 shall apply mutatis mutandis to the brokering of medicinal products.

(2) Persons may only broker medicinal products if they are registered with the National Agency for Medicines and Medical Devices, when their permanent address referred to in paragraph (1) is in Romania. Those persons shall submit, at least, their name, corporate name and permanent address in order to register. They shall notify the National Agency for Medicines and Medical Devices of any changes thereof within 30 days. The National Agency for Medicines and Medical Devices shall enter the information referred to in the first subparagraph in a register that shall be publicly accessible.

(3) The guidelines referred to in Article 795 shall include specific provisions for brokering.

(4) This Article shall be without prejudice to Article 823. When the medicinal product broker is registered in Romania, inspections referred to in Article 823 shall be carried out under the responsibility of the National Agency for Medicines and Medical Devices. If a person brokering medicinal products does not comply with the requirements set out in this Article, the National Agency for Medicines and Medical Devices may decide to remove that person from the register referred to in paragraph (2). The National Agency for Medicines and Medical Devices shall notify that person thereof." The implementation of the community legal status in matters of medicinal product sale at a distance to the public is to be the object of a separate ruling amending Law of Pharmacy no. 266/2008.

88. Under Article 823, paragraph (1) is amended as follows:

"Art. 823. - (1) The National Agency for Medicines and Medical Devices shall, in cooperation with the European Medicines Agency, ensure that the legal requirements governing medicinal products are met, by means of unannounced inspections, if need be; where appropriate, the National Agency for Medicines and Medical Devices requires its own control laboratory or a NAMMD certified/approved control laboratory to carry out tests on samples. This cooperation shall consist in sharing information with the European Medicines Agency on both inspections that are planned and that have been conducted. The National Agency for Medicines and Medical Devices, Member States and the European Medicines Agency shall cooperate in the coordination of inspections in third countries. The inspections shall include but not be limited to the ones mentioned in paragraphs (1^1) to (1^6)."

89. Under Article 823, 8 new paragraphs are introduced after paragraph (1), paragraphs (1^1)-(1^8), which read as follows:

"(1^1) Manufacturers located in the European Union or in third countries and wholesale distributors of medicinal products shall be subject to repeated inspections.

(1^2) The National Agency for Medicines and Medical Devices shall have a monitoring system including inspections at an appropriate frequency, depending on the risk level, at the premises of the manufacturers, importers, or distributors of active substances located in Romania, and effective follow-up thereof. Whenever it considers that there are grounds for suspecting non-compliance with the legal requirements laid down in this Directive, including the principles and guidelines of Good Manufacturing Practice and Good Distribution Practices referred to in point f) of Article 754 and in points b) and c) of Article 756, the National Agency for Medicines and Medical Devices may carry out inspections at the premises of:

a) Manufacturers or distributors of active substances located in third countries;

b) Manufacturers or importers of excipients.

(1^3) Manufacturers or importers of excipients (1^1) and (1^2) may also be carried out in the European Union and in third countries at the request of the National Agency for Medicines and Medical Devices, of a Member State, the European Commission or the European Medicines Agency.

(1^4) Inspections may also take place at the premises of marketing authorisation holders and of brokers of medicinal products.

(1^5) In order to check whether the data submitted to obtain a certificate of compliance is in line with the monographs of the European Pharmacopoeia, the National Agency for Medicines and Medical Devices may answer the requests of the European Commission/the European Medicines Agency for performance of such inspections when the concerned starting material is subject to a monograph of the European Pharmacopoeia.

(1^6) The National Agency for Medicines and Medical Devices may carry out inspections of starting material manufacturers at the specific request of the manufacturer.

(1^7) Inspections shall be carried out by officials representing the National Agency for Medicines and Medical Devices, who shall be empowered to:

a) Inspect the manufacturing or commercial establishments of manufacturers of medicinal products, of active substances or of excipients, and any laboratories employed by the holder of the manufacturing authorisation to carry out checks pursuant to the provisions of Article 725;

b) Take samples including with a view to independent tests being carried out by a laboratory of the National Agency for Medicines and Medical Devices or a National Agency for Medicines and Medical Devices certified/approved control laboratory; costs of samples taken in the frame of the surveillance activity are borne by the manufacturer or the distribution unit, as applicable; costs of tests performed by the National Agency for Medicines and Medical Devices or the National Agency for Medicines and Medical Devices certified/approved control laboratory are covered from the National Agency for Medicines and Medical Devices budget if the product is complaint or by the liable manufacturer or distributor, if the product is non-complaint;

c) Examine any documents relating to the object of the inspection, subject to the national provisions in force placing restrictions on these powers with regard to the description of the manufacturing method;

d) Inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any firms employed by the marketing authorisation holder to perform the activities described in Chapter X.

(1^8) Inspections shall be carried out in accordance with the guidelines referred to in Article 823^1."

90. Under Article 823, paragraphs (3)-(8) are amended and shall read as follows:

"(3) After every inspection as referred to in paragraph (1), the National Agency for Medicines and Medical Devices shall report on whether the inspected

entity complies with the principles and guidelines of Good Manufacturing Practice and Good Distribution Practices referred to in Articles 756 and 795, as applicable, or on whether the marketing authorisation holder complies with the requirements laid down in Chapter X; the content of those reports is communicated to the inspected entity. Before adopting the report, the National Agency for Medicines and Medical Devices shall allow the inspected entity concerned to submit comments.

(4) Without prejudice to any arrangements concluded between the European Union and third countries, the National Agency for Medicines and Medical Devices, the European Commission or the European Medicines Agency may require a manufacturer established in a third country to submit to an inspection as referred to in this Article.

(5) Within 90 days of an inspection as referred to in paragraph (1), a certificate of Good Manufacturing Practice or Good Distribution Practices shall, when applicable, be issued to the inspected entity if the outcome of the inspection shows that it complies with the principles and guidelines of Good Manufacturing Practice / Good Distribution Practices as provided for by national legislation; if inspections are performed as part of the certification procedure for the monographs of the European Pharmacopoeia, a Good Manufacturing Practice certificate shall be drawn up.

(6) The National Agency for Medicines and Medical Devices shall enter the issued certificates of Good Manufacturing Practice and Good Distribution Practices into the European Union database managed by the European Medicines Agency on behalf of the European Union. Pursuant to paragraph (7) of Article 761^{1}, the National Agency for Medicines and Medical Devices may also enter information in that database regarding the registration of importers, manufacturers and distributors of active substances. The database shall be available to the public.

(7) If the outcome of the inspection referred to in paragraph (1^{7}) or the outcome of an inspection conducted on a medicinal product / active substance distributor or an excipient manufacturer shows that the inspected unit is not compliant with legal requirements and/or Good Manufacturing Practice or Good Distribution Practice principles and guidelines provided in national legislation, information shall be entered into the European Union database referred to in paragraph (6).

(8) Inspections referred to under point d) of paragraph (1^{7}) may also be performed on request by an EU Member State, the European Commission or the European Medicines Agency."

91. Two new Articles are introduced after Article 823, Articles 823^{1} and 823^{2}, which read as follows:

"Art. 823^{1}. - The National Agency for Medicines and Medical Devices shall apply the detailed guidelines laying down the principles applicable to inspections referred to in Article 823, as adopted by the European Commission; the National Agency for Medicines and Medical Devices shall transpose the form and content

of the authorisation referred to in Articles 748 (1) and 788 (1), of the reports referred to in Article 823 (3), of the certificates of Good Manufacturing Practice and of the certificates of Good Distribution Practices referred to in Article 823(5), set up by the European Medicines Agency.

Art. 823^{2}. - (1) Pursuant to Article 755^{1}(3), Romania takes count of the list of active substance exporting third countries set up by the European Medicines Agency on request by an exporting third, based on assessment of whether that country's regulatory framework applicable to active substances exported to the European Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the European Union.

(2) The National Agency for Medicines and Medical Devices cooperate with the European Commission, the European Medicines Agency and competent authorities in the other member States in conducting the assessment referred to in paragraph (1)."

92. Article 828 is amended as follows:

"Art. 828. - (1) The National Agency for Medicines and Medical Devices shall suspend, withdraw or change a marketing authorisation whenever it deems that the medicinal product is harmful or lacks in therapeutic efficacy, its risk/benefit ratio is unfavourable or its qualitative and quantitative composition is different from that declared; therapeutic efficacy is absent if the conclusion is reached that therapeutic outcomes cannot be achieved with the medicinal product concerned.

(2) A marketing authorisation can also be suspended, withdrawn or changed if data presented in support of the application referred to in Articles 702, 704, 705, 706, 707 or 708 are inaccurate or have not been changed pursuant to Article 728, when conditions established in Articles726^{1}, 727 or 727^{1} have not been met or when controls referred to in Article 824 have not been conducted.

(3) Paragraph (2) also applies to cases when medicinal product manufacturing is not compliant with information provided according to point e) of Article 702(4), or when controls are not carried out in compliance with the control methods described pursuant to point i) of Article 702(4)."

93. After Article 829, a new article, Article 829^{1}, is added, reading as follows:

"Art. 829^{1}. - (1) Competent authorities shall adopt regulatory documents whose aim is to prevent medicinal products that are suspected to present a danger to health from reaching the patient.

(2) The regulatory documents referred to paragraph (1) shall cover the receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products. They shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by the National Agency for Medicines and Medical Devices from all relevant actors in the supply chain both during and outside normal working hours. Such regulatory documents shall also

make it possible to recall, where necessary with the assistance of healthcare professionals, medicinal products from patients who received such products.

(3) If the medicinal product in question is suspected of presenting a serious risk to public health, the National Agency for Medicines and Medical Devices identified shall, without any delay, transmit a rapid alert notification to all Member States and all actors in the supply chain in Romania. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.

(4) By 22 July 2013, the National Agency for Medicines and Medical Devices shall notify the Commission of the details of their respective national systems referred to in this Article."

94. Three new Articles are introduced after Article 830, articles 830^1-830^3, which read as follows:

"Art. 830^1. - By 2 January 2013, the National Agency for Medicines and Medical Devices shall notify the European Commission on internal rule provisions adopted for transposition of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal product and notify any changes thereof without delay.

Art. 830^2. - The National Agency for Medicines and Medical Devices shall organise meetings involving patient and consumer organisations/associations and, as necessary, enforcement officers in Romania, in order to communicate public information about the actions undertaken in the area of prevention and enforcement in view of combating the falsification of medicinal products.

Art. 830^3. - In applying this Directive, the Ministry of Health and the National Agency for Medicines and Medical Devices shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities."

95. Under Article 836 paragraph (1), points a), c), d), f), g) and h) are amended and shall read as follows:

"a) A fine ranging from 10,000 lei to 30,000 lei, applied to the manufacturer and closure of the unit, when the manufacturing unit operates without a manufacturing authorisation issued by the National Agency for Medicines and Medical Devices; the wholesale distributor shall be punished with the same penalty, as well as with the closure of the wholesale distribution unit for medicinal products that operates without an authorisation issued by the National Agency for Medicines and Medical Devices;

.....

c) A fine ranging from 5,000 to 10,000 lei, applied to the manufacturer/importer or wholesale distributor, as appropriate, for performance

of other activities than those authorised in the manufacturing/wholesale distribution unit, for the supply performed by the manufacturer/wholesale distributors of medicinal products to other units unauthorised by the National Agency for Medicines and Medical Devices (wholesale distributors) or by the Ministry of Health (pharmacies, drugstores, other units authorised to perform healthcare activities) in accordance with the law, the distribution (performed by suppliers) to drugstores of other medicinal products than those released without medical prescription, the participation of unqualified persons in technical operations requiring specialised training in the fields of manufacturing and distribution processes, as well as the non-compliance of the provisions related to the imprinting of the medicinal products' leaflets, advertising, reporting the changes occurred in the manufacturing/distribution activity, non-compliance with Good Practice Rules in the activity of pharmacovigilance performed by the Marketing Authorisation Holder, the participation of unqualified persons to technical operations requiring specialised qualification in the manufacturing and wholesale distribution processes, as well as the non-compliance with the provisions concerning the imprinting and package leaflet of medicinal products, advertising, reporting the changes occurred in the manufacturing/import/distribution activity, the non-compliance with Good Practice Rules in the activity of pharmacovigilance performed by the Marketing Authorisation Holder, non-compliance with storage conditions of medicinal products and with the export legislation, the donation and supply of medicinal product samples;

d) A fine ranging from 10,000 to 30,000 lei, applied to the manufacturer/importer or wholesale distributor in case of non-compliance with the conditions for authorisation of the unit handling the manufacture/import/product distribution processes or in case of non-compliance with the Guideline on the Good Manufacturing Practice and with the Guideline on the Good Wholesale Distribution Practice;

.....

f) A fine ranging from 5,000 to 10,000 lei, due to the absence of the head pharmacist or of his/her *locum tenens* during the working schedule of the distribution unit; the absence of the person responsible for the quality or of his/her *locum tenens* during the working schedule of the unit, as far as distribution units authorised for purchase/marketing activities are concerned, shall be fined the same amount;

g) A fine ranging from 10,000 to 30,000 lei and suspension of the authorisation of the manufacturer/wholesale distribution unit for a one-year period, if any of the infringements detected during a 3-month period reoccurs, as stipulated under c) and e);

h) A fine ranging from 5,000 to 20,000 lei and suspension of the wholesale distribution authorisation, in case of non-compliance with the Guideline on Good Wholesale Distribution Practice, until the findings are remedied; brokers who fail

to comply with the specific provisions of the Guideline on Good Wholesale Distribution Practice shall be fined the same amount;".

96. Under Article 836 paragraph (1), point î) is repealed.

97. 13 new points are introduced under Article 836 (1), after point k), points l)-v), which read as follows:

"l) A fine ranging from 10,000 to 30,000 lei and prohibition of the activity if brokers do not notify the National Medicines Agency about the performance of brokerage of medicinal products/active pharmaceutical substances on Romanian territory;

m) A fine ranging from 10,000 to 30,000 lei and temporary suspension of the marketing authorisation for a 6-month period, if the importer fails to fulfil his/her commitment to submit to the National Agency for Medicines and Medical Devices the import status and if manufacturers / importers / wholesalers fail to comply with their commitment concerning the submission to the National Medicines Agency of the report regarding distributed products, in accordance with the law;

n) A fine ranging from 10,000 to 30,000 lei, in the event of non-compliance with the obligation referred to in Art. 729 (2);

o) A fine ranging from 10,000 to 20,000 lei, in the event of incorrect release of the medicinal product batch manufactured/imported in Romania performed by the qualified person of the manufacturer/importer;

p) A fine ranging from 10,000 lei to 30,000 lei and suspension of the certificate attesting the "qualified person" status for one year, in case of reoccurrence of the respective infringement during a 6-month period, as shown in n); the suspension shall be abolished only on account of a proof attesting the fact that the qualified person has undertaken relevant training throughout the period of suspension;

q) A fine ranging from 10,000 lei to 30,000 lei applied to the investigator and suspension of the study in case of performance in Romania of clinical trials which have not been authorised by the National Agency for Medicines and Medical Devices (NAMMD) or for which the National Ethics Committee/Institutional Ethics Committee has issued an unfavourable opinion;

r) A fine ranging from 10,000 lei to 30,000 lei applied to the investigator and suspension of the study in case of performance in Romania of clinical trials in units which are unauthorised for performance of clinical trials in the field of medicinal products for human use by the Ministry of Health;

s) A fine ranging from 10,000 to 20,000 lei applied to the sponsor in the event of supply of an investigator/institution with the investigational medicinal product before it was granted full necessary documentation (e.g. approval of the National Ethics Committee/Institutional Ethics Committee and of the National Agency for Medicines and Medical Devices;

ş) A fine ranging from 2,000 to 5,000 lei applied to the sponsor who does not fulfil his/her obligations concerning the evaluation of the safety of the investigational medicinal product during the study;

t) A fine ranging from 2,000 to 5,000 lei applied to the investigator if he/she fails to fulfil his/her obligations on reporting serious adverse events arising after the administration of the investigational medicinal product during the study;

ţ) A fine ranging from 10,000 to 30,000 lei in the event of not granting the inspection staff of the National Agency for Medicines and Medical Devices access to the documents and facilities of the inspected unit;

u) A fine ranging from 10,000 to 30,000 lei applied to the manufacturer/importer/supplier of active substances in the event of non-compliance with the provisions of this Law related to the manufacturing, importation, distribution and export of active substances;

v) A fine ranging from 10,000 to 30,000 lei applied to the manufacturer of medicinal products in the event of non-compliance with the provisions of Art. 754 f)."

98. Under Article 836, paragraph (2) is amended as follows:

"(2) The offences and penalties provided in paragraph (1) shall be made by inspectors of the National Agency for Medicines and Medical Devices and the Ministry of Health, as appropriate."

Article II. - (1) The competent authorities shall adopt provisions / provisions to ensure implementation of art. I, section 73, 74, 76 and 77 of this law within three years from the date of publication of the delegated acts referred to in art. I point 77 of this Law.

(2) The persons referred to in Art. 761^1 paragraph (1) and Art. 796^2 paragraph (2) of Law no. 95/2006 on healthcare reform, as amended, who started work before the entry into force of this legislation shall submit the registration form to the National Agency for Medicines and Medical Devices until March 2, 2013.

Art. III. - Paragraph (2) of Article 16 of Law no. 584/2002 on measures to prevent the spread of AIDS in Romania and protection of people living with HIV or AIDS, published in the Official Gazette of Romania, Part I, no. 814 of November 8, 2002, as amended, is amended as follows:

"(2) The financing of therapeutic activities and medical treatment is done from the budget of the Ministry of Health or, where appropriate, from the budget of the National Health Insurance House, in accordance with the law."

Art. IV. – Article 5 of Law 263/2004 regarding the insurance of continuity of primary medical assistance through primary care clinics, published in the Official Gazette of Romania, Part I, No. 568 of 28 June 2004, as amended, is amended as follows:

"Art. 5. – The attributions of public health directors on the functioning of primary care clinics are the following:

a) Territorial assignation of cities to permanent centres;

b) Control of the planning and performance of the activity;

c) Insurance of approval of monthly scheduling of physicians ensuring the continuity of primary medical assistance in primary care clinics, established by the physician coordinator of the centre, until day 25 of the current month for the following month."

Art. V. – The national plan for enforcement of the International Health Regulation (2005) referred to in Art. 5 b) of Government Decision No. 758/2009 for enforcement of the International Health Regulation (2005) shall ensure the handling of all provisions of the International Health Regulation (2005), from the scope of responsibility of each competent authority, and shall be submitted for approval through common order of competent authorities in view of enforcement of International Health Regulation (2005) provisions.

Article VI. - Article I, sections 1-22, 24-26, 31-33, 36-40, 42, 45-55 and 60 and Art. III and IV shall come into force on 1 March 2013.

Art. VII. - In 2013, the financing of national healthcare programs is also performed through transfers from state budget and personal revenues, through the Ministry of Health, to the Single National Social Health Insurance Fund for:

a) The discharge of registered payment liabilities limited to commitment appropriations approved for national healthcare programs whose financing is ensured until 1 March 2013 through transfer from the budget of the Ministry of Health to the budget of the National Social Health Insurance Fund;

b) The discharge of registered payment liabilities limited to commitment appropriations approved for the National program of transmissible diseases whose financing is ensured until 1 March 2013 from the budget of the Single National Social Health Insurance Fund.

This Emergency Ordinances transposes Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, published in the Official Journal of the European Union, L, 174/74 of 1 July 2011, excepting Art. 1 point 20.

PRIME MINISTER
VICTOR-VIOREL PONTA

Countersigned:
Minister of Health,
Raed Arafat
Minister of Administration and Internal Affairs,
Mircea Duşa
Minister-delegate for administration,
Radu Stroe

Minister of National Defence,
Sebastian Huluban,
Secretary of State,
Minister of Labour, Family and Social Protection
Mariana Campeanu
Minister for Infrastructure and Transport,
Ovidiu Ioan Silaghi
Vice prime minister,
Minister of Public Finances,
Florin Georgescu

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