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EMERGENCY ORDINANCE no. 2 of 29 January 2014
on amendment of Law no. 95/2006 on healthcare reform and of certain regulatory acts

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Considering that, as an EU Member State with full rights, it is Romania's duty to transpose and implement Directives adopted by the European Union,

as well as the negative consequences of failure to urgently promote this regulatory act which ensures the primary framework for transposition of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (deadline for transposition: 25 October 2013),

and that any delay of Romanian authorities may result in non-compliance with its duties as a Member State, in accordance with Article 258 of the Treaty on the functioning of the European Union,

given that the European right is violated when, on expiry of the procedural deadline for answering consisting of two month after the transmission of the motivated approval, Member States have not yet adopted internal legal measures for transposition, regardless of compliance thereof during the legal procedure,

considering that Communication of the European Union SEC (2011) 1.024 of 1 September 2011 has established the minimal lump sum of 1,710,000 Euro for Romania, the value of the national factor "n" for calculation of comminatory damages is 3.29, and the damages consisting of about 2,000 – 130,000 euro/day of delay, which could have major impact upon the state budget,

considering that the deadline undertaken by Romanian authorities [ref. SANCO D4/IS/ac ARES (2012)] for amendment of deficiencies concerning transposition of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells was June 2013,

in order to rectify deficient transposition of Article 118a of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 for amendment of 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, considering the need to avoid the opening of the infringement procedure, as well as to avoid enforcement of pecuniary sanctions against Romania, in accordance with Article 260 (3) of the Treaty on the functioning of the European Union, accelerating the mechanism for enforcement of pecuniary sanctions if the European Commission, appealing to the Court of Justice for noncompliance with its duties, considers that the Member State has not fulfilled its duty to report the measures for transposition of a Directive adopted in accordance with a legislative procedure,

considering that, as a Member State, Romania can only be considered to have fulfilled its duty to ensure complete transposition of this Directive after submission of all acts for transposition of this Directive, thus avoiding the opening of the infringement procedure,

for ensuring patient rights as granted through Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011, scheduled for transposition on 25 October 2013, and avoidance of patients suing for reimbursement rights in accordance with ECJ jurisprudence,

given this year's Minister' of Foreign Affairs request by notification no. K1/450 of October 23 to the Minister of Health for immediate adoption of regulatory acts for transposition of the European document,

considering the Zero Tolerance Policy adopted by the Commission for cases of non-transposition, according to COM (2012) 259 (Communication on Better Governance for the Single Market), requiring Member States to assume a zero-tolerance objective concerning transposition of directives translated with 0% transposition deficit and conformity deficit,

considering that, according to the Minister's of Foreign Affairs Notification to the Romanian Prime-minister about the alarming tendency for significant increase in the number of outstanding directives through letter no. K1/415/11.10.2013 on fulfilment of obligations to transpose and notify measures for directive transposition, introduced in the Government meeting of 16 October, Romania displays a 2.3% transposition deficit,

considering negative consequences of lack of urgent promotion of this regulatory act ensuring transposition of Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC, as regards pharmacovigilance, having the deadline for transposition 28 October 2013,

to reduce the risk of opening action for non-compliance with Member State duties, in accordance with Article 258 of the Treaty on the functioning of the European Union,

taking into account that transposition of this Directive ensures the necessary and mandatory conditions for a high quality medical activity for Romanian citizens,

considering that failure to implement such immediate measures and their implementation rules, through government ordinance, would lead to major malfunctions with negative effects upon the population's health condition and would impair efficient use of human and financial resources of the health system,

considering the major role of the pharmacovigilance activity in safeguarding public health from potential adverse reactions of medicinal products and in obtaining the complete safety profile of medicinal products, taking into account the fact that, according to Article 2 of Law No. 157/2005 for the ratification of the Treaty between the Kingdom of Belgium, the Czech Republic, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, the Hellenic Republic, the Kingdom of Spain, the French Republic, Ireland, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Hungary, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, the Republic of Slovenia, the Slovak Republic, the Republic of Finland, the Kingdom of Sweden, the United Kingdom of Great Britain and Northern Ireland (Member States of the European Union) and the Republic of Bulgaria and Romania concerning the accession of the Republic of Bulgaria and Romania to the European Union, signed by Romania in Luxembourg on 25 April 2005, Romania must fulfil its duties resulting from the Accession document, from provisions of EU constitutional treaties and the other binding community regulations,

considering the need to avoid national legislative parallels and establishment of the legal framework for enforcement of provisions of Regulation (EC) no. 1.223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, entered into force on 11 July 2013, date of repeal of Directive no. 76/768/EEC of the Council of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, imposing urgent repeal of Law no. 178/2000 on cosmetic products,

considering the need to provide medical services in line with the community's real needs, direct involvement of local public administration authorities in improvement of medical service addressability and accessibility, increased public access to preventive and curative medical services, decrease of health system bureaucracy, warranty of non-discriminating access to basic medical services, irrespective of income,

to eliminate malfunctioning potentially caused by decentralisation and considering the need to cover all fields posing a major risk for the population with structures and activities able to prevent or limit the detrimental effects upon the population's overall health condition,

considering the need for emergency adoption of the organisational framework of the health system in accordance with changes resulting from decentralisation, so as not to affect the quality of medical assistance and public health,

for supplementation of the organisational framework characteristic to emergency medicines by assigning certain attributions to family physicians, considering the stringent need for competent staff coverage in rural areas lacking specialised staff following closure of 67 hospitals, as well as for reduction of the pressure from exponentially increased demand on emergency care,

considering the necessity to match the compounds of the emergency system, aiming at increased efficiency and expedited action to save lives, as well as coordination of actions and their inclusion into an integrated system ensuring higher efficiency in case of earthquakes, natural disasters or cataclysms, lately posing an increasing threat on the public,

considering that one of the structural reference criteria of the agreement with the IMF, the World Bank and the European Commission is elaboration of a basic set of medical services inside the existing frame of expenses and establishment of the field of private health insurance, scheduled for approval assumed within the agreement mentioned at the end of 2013, thus enabling their enforcement in 2014,

considering country-specific recommendations (CSRs) endorsed by the Summer European Council of 27 - 28 June 2013, the objectives undertaken via the National Reform Programme 2013 - 2014, strategic document allowing information and governmental control of outcomes of implementation of the Europe 2020 strategy in Romania and also the basis for the reporting documents to the European Commission (COM) in the context of the European Semester, and that the major action channels for the following year, as well as assessment of the national achievements of 2013, are to be the object of the COM report – Yearly analysis of economic growth,

considering the need to regulate the organisation, manner of performance and coordination of outpatient assistance, as well as its manner of financing, for diminished costs as resulting from prolonged or ineffectual hospitalisation, as well as reorientation of funds to other areas of the health system,

in the context of granting particular importance to preventive medical services, thus making such services more accessible, at the same time with reduction in number of hospital admissions in healthcare facilities with beds and grant of increased financing for services in outpatient facilities,

considering the restrictive conditions imposed to candidates for the hospital manager position, as regards the type of further training and the training provider, as well as the status as academic or primary physician,

considering the need to broaden access to the hospital manager position for professionals specialised in management/health management, as well as the opportunity for physicians, hospital managers, to perform their job without affecting the managerial work, maximum performance in management of hospital facilities,

to correlate legal provisions on transfer of funds from the Ministry of Health budget to local budgets, through special structures to local public administration authorities,

considering that investments performed in hospitals in the healthcare network of local public administration authorities, whose main credit officers are local/county councils, have not been allocated in the annexes to the budget of the Ministry of Health,

considering the necessity to ensure the possibility of funding from the Ministry of Health budget, until completion, of new and ongoing investment works which, on the date of hospital management transfer, received financing through annual investment programmes, provided for as annex to the budget of the Ministry of Health, ongoing on the date of management transfer, under different stages of performance,

considering that funds not allocated from the budget of local public administration authorities may not be approved through Order of the Minister of Health, and such funding allocation by categories such as investments must, first and foremost, consider the strategy of the Ministry of Health on supply and modernisation of the health infrastructure, established through special structures of the Ministry, following reorganisation of the healthcare system,

considering the emergency character of such measures and in high demand for provision of a legal framework, as harmonised as possible, correlated with the other regulatory acts in force,

considering that the major impact of such issues upon the manner of granting medical services within the social health insurance system, as well as upon the health condition of the Romanian population also affect the public interest, representing emergency and extraordinary situations whose regulation cannot be delayed,

considering the undertaking of the Romanian Government as regards international financial bodies on amendment of current legislation for implementation of comprehensive reform of the healthcare system, ensuring financial tenability of this system, increased efficiency of expenses in this field and improvement of its outcomes, urgent adoption of this emergency ordinance is required, since failure to comply with the structural criterion witin the assumed term may endanger maintenance of the agreement with the International Monetary Fund (IMF), the World Bank and the European Commission.

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

the Government of Romania hereby adopts this Emergency Ordinance.

ARTICLE 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. Article 2 (8) is amended as follows:

"(8) The responsibility for public health insurance lies with the Ministry of Health, county and Bucharest public health directorates and other special structures of the Ministry of Health, the National Health Insurance House, special structures subordinated to ministries and institutions provided with their own healthcare network, as well as with local public administration authorities."

2. Under Article 4 (1), a new point, g), is introduced after point f), which reads as follows:

"g) protocols standardised at national level – documents issued by specialised commissions of the Ministry of Health in cooperation with special medical associations and on approval of the Romanian College of Physicians, instrumental in organisation of transposition at national level of recommendations for clinical practice, transparently and systematically developed through methods of evidence-based medicine meant for decision targeting on health interventions."

3. Article 4 (2) is amended as follows:

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

4. Under Article 5, point o) is amended as follows:

"o) incorporation of public health priorities into national policies and strategies and into sectorial strategies for sustainable development;".

5. Under Article 7, three new points, j), k) and l), are introduced after point i), which read as follows:

"j) increase in responsiveness to calamity, disaster and emergency situations, including those determined by climate changes;
k) assessment of the impact upon all activity sectors influencing health factors;
l) an intersectoral approach to healthcare through coordinated action of all institutions to improve public health."

6. Under Article 8, a new paragraph, (2), is introduced, which reads as follows:

"(2) Regulation drafts containing provisions influencing health condition factors shall be accompanied by impact studies on health, as a tool for decision substantiation, performed in accordance with the methodology approved through Order of the Minister of Health."

7. On 1 August 2014, paragraph (5) of Article 9 shall be repealed.

8. Under Article 11, point b) is amended as follows:

"b) other institutions and Ministry of Health specialised structures performing activities in the field of public health at national, regional or local level."

9. Article 15 is amended as follows:

"ARTICLE 15
Legal institutions and Ministry of Health specialised structures performing activities in the field of public health at national, county and local level, subordinated to, coordinated by or under the authority of the Ministry of Health, except for the NHIH and health insurance houses, are set up, reorganised and dissolved through Government Decision."

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

"a) establishes national public health priorities;
.....
g) approves, through Order of the Minister of Health, standardised protocols at national level, issued by specialised commissions of the Ministry of Health, on consultation with special medical associations."

11. Article 16 (1^1) is amended as follows:

"(1^1) In conduct of its assignments and responsibilities mentioned under (1), the Ministry of Health and its special structures have full access and use data of the Health Insurance Information Platform, in line with provisions of Law no. 677/2001 on the protection of individuals with regard to the processing of personal data and the free movement of such data, as amended."

12. Under Article 16 (1), two new points, h) and i), are introduced after point g), which read as follows:

"h) performs the role of centralised procurement unit through a specialised structure in accordance with Emergency Government Ordinance no. 71/2012 on assignment of the Ministry of Health as a central public procurement unit, approved as amended through Law no. 184/2013;
i) drafts the policy and strategies in the health information system, for integrated and interoperable use of its components."

13. On 1 August 2014, Article 17 (2) o) is repealed.

14. Under Article 20, two new paragraphs, (3) and (4), are introduced after (2), which read as follows:

"(3) Local public administration authorities are required to submit to the institutions of the Ministry of Health the data and documents containing information required for set up of reports mentioned under (1), as well as those established through legal regulations in force for Romania’s reporting to the European Commission.
(4) Failure to submit the information mentioned under (1) by public and/or private healthcare facilities is considered an offence and punishable by a fine amounting to 10,000 to 20,000 lei for legal persons."

15. Article 29 is amended as follows:

"ARTICLE 29
(1) Preventive and curative medical assistance is ensured through:
a) outpatient medical cabinets of family physicians and other types of physicians, diagnosis and treatment centres, medical centres, health centres, laboratories, as well as other public and private health facilities;
b) public and private healthcare bed containing facilities.
(2) The facilities mentioned under (1) are required to ensure mobility conditions for medical information submitted in electronic format, by using the system of the patient's health electronic record. If another informatics system is employed, it must be compatible with this system of informatics platform for health insurance; in such case, providers are required to ensure safety and confidentiality conditions during the data submission process."

16. A new Article, 43^1, is introduced after Article 43, which reads as follows:

"ARTICLE 43^1
The methodological norms on public health activity are elaborated by public health structures and approved through Order of the Minister of Health."

17. Under Article 45, paragraph (1), points a) and c) are amended as follows:

"a) The set of national healthcare programs – set of multiannual actions oriented towards the main intervention fields of public health assistance;
.....
c) the implementation of national healthcare programs – organisation of human, material and financial resources from special facilities, in view of providing goods and services for the beneficiaries of these programs or changes in their demeanour, in reply to certain health needs identified from objective data."

18. On 1 August 2014, point e) of Article 45 (1) is repealed.

19. On 1 August 2014, Article 45 (2) is repealed.

20. Article 47 is amended as follows:

"ARTICLE 47
(1) The set of national healthcare programs are set up, coordinated and assessed by the Ministry of Health through a specialised structure, assigned through Government Decision.
(2) In view of elaboration of national healthcare programs, the specialised structure collaborates with NHIH and with authorities, institutions and non-governmental organisations.
(3) The beneficiaries of national healthcare programs are insured persons, in accordance with the provisions of Article 211 (1), as well as the persons residing in Romania, who do not obtain revenues from work, retirement or other sources.
(4) In case of epidemiological risk, the beneficiaries of national healthcare programs are the persons mentioned under (3), as well as the ones passing through Romania."

21. On 1 August 2014, paragraphs (1) and (4) of Article 48 are repealed.

22. Under Article 48, paragraphs (2) and (3) are amended as follows:

"(2) The set of national healthcare programs and the conditions and terms required for layout are approved through Government Decision, at the proposal of the Ministry of Health.
(3) The technical norms for enforcement of national healthcare programs are approved through joint Order of the Minister of Health and of the President of the National Health Insurance House."

23. On 1 August 2014, paragraph (1) of Article 49^1 is repealed.

24. Under Article 49^1, (2) is amended as follows:

"(2) National healthcare programs are implemented by special facilities according to the agreements signed with health insurance houses. Public institutions which implement national healthcare programs ensure the gratuitousness of all services required for performance of national healthcare programs."

25. On 1 August 2014, Article 50 is repealed.

26. On 1 August 2014, Article 51 is repealed.

27. Article 52 is amended as follows:
"ARTICLE 52
The attributions of authorities in the public health field and of special facilities in the field of national healthcare programs are established through Government Decision."
28. On 1 August 2014, Article 53 is repealed.
29. Under Article 54, paragraphs (1) and (4) are amended as follows:
"ARTICLE 54
(1) National healthcare programs are financed as follows:
a) from budget of the Ministry of Health, state budget and own revenues by transfer to the budget of the Single National Fund of Social Health Insurance;
b) from budget of the Single National Fund of Social Health Insurance;
c) from other sources, including donations and sponsorships, in accordance with the law.
.....
(4) The manner of settlement for goods and services granted in the context of national healthcare programs is established through Government Decision."
30. On 1 August 2014, paragraphs (3), (5) and (6) of Article 54 are repealed.
31. Article 57 is amended as follows:
"ARTICLE 57
The Ministry of Health and the National Health Insurance House ensure the funds for financing of national healthcare programs."
32. Under Article 63, point e) is amended as follows:
"e) ensures the consistency of primary medical assistance through emergency consultations recorded through emergency national system, outside the regular working schedule of family medicine cabinets, while on guard, via medical permanence centres;".
33. Article 66 is amended as follows:
"ARTICLE 66
Primary medical assistance and consistency in this field are performed in family medicine cabinets and medical permanence centres set up in accordance with the law."
34. Under Article 72, point a) is amended as follows:
"a) priority interventions in medical-surgical emergencies, as well as in acute disorders;".
35. Under Article 72, a new point, k), is introduced after point j), which reads as follows:
"k) the grant of consultations mentioned under point a) recorded through the national emergency system, outside the working schedule of family medicine cabinets."
36. Under Article 91, a new paragraph, (1^1), is introduced after paragraph (1), which reads as follows:
"(1^1) County ambulance services may be organised and operate within areal or county structures according to operative criteria."
37. Under Article 93, three new paragraphs, (5^5) - (5^7), are introduced after (5^4), which read as follows:
"(5^5) The structure of emergency admission facilities of emergency county hospitals may include emergency admission compartments of healthcare facilities from the administrative-territorial surrounding of the respective county.
(5^6) Emergency admission compartments mentioned under (5^5) are financed from Ministry of Health revenues, from state budget and own revenues of this Ministry, according to the approved budget.
(5^7) The inclusion of emergency admission compartments within an emergency admission unit is approved through Order of the Minister of Health, within the budget allocated for financing emergency rooms, and according to criteria established through Order of the Minister of Health as suggested by a special commission of the Ministry of Health."
38. Under Article 93, a new paragraph, (8), is introduced after (7), which reads as follows:

"(8) For county ambulance services, namely for the Bucharest-Ilfov Ambulance Service, through Government Decision, the set-up of an entirely own revenue financed activity, namely health transportation upon request, both internally and externally, and ensurance of medical assistance upon request for sport and other public events, are approved."

39. A new title, V^1, is introduced after Title V "The national system for emergency medical assistance and qualified first aid", which reads as follows:

"TITLE V^1

Special outpatient medical assistance

CHAPTER I

General provisions

ARTICLE 126^1

The object of this Title is the regulation of the field of special outpatient medical assistance, ensured through clinical, paraclinical and dental medical services.

ARTICLE 127^1

The goals of special outpatient medical assistance are:

a) provision of preventive services, establishment of the diagnosis and performance of an outpatient treatment in view of safeguarding, maintaining or improving the health condition of the population;

b) ensurance of continuity of diagnosis and therapy of health services by vertical integration with primary medical and hospital assistance.

ARTICLE 128^1

(1) The special outpatient medical assistance is ensured by special physicians in collaboration with other specialised staff, authorised in accordance with the law, and is granted through the following medical structures:

a) specialised medical cabinets organised in accordance with the legislation in force on organisation and operation of medical cabinets;

b) special outpatient medical facilities, organised in accordance with legal provisions in force, functioning independently or within hospitals;

c) special outpatient medical cabinets from hospitals which do not belong to the hospital’s integrated/special outpatient unit;

d) authorised providers of special care at home;

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

(2) The following can be included within the special outpatient medical facilities mentioned under (1) b):

a) laboratories/centres of radiology and medical imagistics, medical analyses, functional investigations, organised in accordance with the law;

b) diagnostic and treatment centres, medical and multifunctional health centres, organised in accordance with the law;

c) special outpatient facilities within hospitals; in accordance with the law;

d) integrated outpatient facilities from hospitals;

e) balneary clinics;

f) paid outpatient departments.

(3) Special medical services are also granted through:

a) TBC clinics;

b) mental health laboratories/centres;

c) one-day hospitalisation with psychiatric profile;

d) stomatological cabinets;

e) mobile medical cabinets and facilities organised in accordance with the norms for enforcement of this Title, approved through Order of the Minister of Health.

CHAPTER II
Performance and coordination of activities from special outpatient facilities

ARTICLE 129^1
(The medical structures mentioned under Article 128^1 may perform the following activities:
a) urgent interventions in medical-surgical emergencies, in accordance with staff skills;
b) preventive actions;
c) medical curative activities;
d) investigation and diagnosis activities;
e) medical rehabilitation activities;
f) activities connected to the medical act;
g) other activities of special medical assistance authorised by the Ministry of Health.
(2) Special physicians/stomatologists perform outpatient assistance activities as follows:
a) as a physical/freelance/authorised person in accordance with legal provisions;
b) organised as special cabinets in accordance with the law;
c) as employees of one of the structures mentioned under Article 128^1 or of legal health facilities containing the special outpatient body.
ARTICLE 130^1
Local public administration authorities can support providers of special medical services, at the level of local communities, in financial, material and administrative terms, also by making available areas meant for medical cabinets/laboratories, in accordance with objective and transparent criteria approved through local council decision.
ARTICLE 131^1
Providers of special medical services have the following specific responsibilities:
a) the record, storage, processing and transmission of data collected from personal activity, in accordance with the norms approved through Order of the Minister of Health;
b) data mentioned under point a) is forwarded to the Ministry of Health, special structures of the Ministry of Health and, as required, to ministries and institutions provided with their own healthcare network, in order to set up a database, at national level, in view of substantiating health policy decisions and to report the data to international bodies;
c) reporting to the NHIH and connected health insurance houses all data mentioned in the signed contracts;
d) to store, safeguard and ensure primary documentation in written and electronic format, as the source of these data, representing the supplier’s archive, in accordance with legal regulations in force.

CHAPTER III
The financing of the activity of special medical services from special outpatient facilities, laboratories and multifunctional medical centres

ARTICLE 132^1
Providers of special medical services can perform their activity through the structures mentioned under Article 128^1.
ARTICLE 133^1
The structures performing activities of special outpatient medical assistance may obtain revenues, as required, from:
a) agreements signed with health insurance houses;
b) agreements signed with private insurers;

c) agreements signed with local public administration authorities;
d) the countervalue of services granted to patients in the context of services not signed with third-party payers and supported by these;
e) research contracts for teaching activities;
f) donations, sponsorships;
g) other sources, in accordance with the law."

40. Under Article 142, a new point, q^1), is introduced after point q), which reads as follows:

"q^1) recipient – person benefitting from organ and/or tissue and/or cell transplant."

*

This point transposes the provisions of Article 3 m) of Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, published in the Official Journal of the European Union, series L, no. 207 of 6 August 2010.

41. Under Article 160, paragraphs (1) and (6) are amended as follows:

"ARTICLE 160

(1) The sampling and transplant of human organs, tissues and cells are performed by special physicians in accredited public or private healthcare facilities. The National Transplant Agency appoints and keeps a register of accredited public or private healthcare facilities, accessible to the public, listing the activities for which each healthcare unit has been accredited. The List of accredited public or private health facilities will be published on the website of the National Transplant Agency and will be permanently updated.

.....

(6) Healthcare facilities accredited for processing and/or using tissues and/or cells keep records concerning their activity, types and quantities of tissues and/or cells procured, tested, preserved, processed, stored and distributed or used in any other manner, as well as concerning the origin and destination of cells intended for human use. These will send a yearly activity report to the National Transplant Agency to be published both on their personal website and on the website of the National Transplant Agency. The provisions of this paragraph are enforced accordingly in case of organ transplantation."

*

This point transposes the provisions of Article 10 (1) and (2) of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, published in the Official Journal of the European Union, series L, no. 102 of 7 April 2004.

42. Under Article 165, paragraphs (2) and (3) are amended as follows:

"(2) The hospital may be public, public with sections/private compartments or simply private. Emergency hospitals are set up and function solely as public hospitals.

(3) Public hospitals, via their sections and private compartments, and private hospitals, may provide medical services discounted from social health insurance, under the conditions established through framework agreement considering the conditions for granting medical assistance within social health insurance system, from other types of health insurance, as well as paid medical services, in accordance with the law."

43. Under Article 165, paragraph (6) is repealed.

44. Under Article 170, paragraph (3) is amended as follows:

"(3) Expenses performed by hospital facilities, in the cases mentioned under (2), are reimbursed from state budget, through budgets of ministries, of managing facilities, as well as

through the budget of administrative-territorial facilities, the budgets of universities of medicine and pharmacy, as required, through Government Decision, within maximum 30 days as of date of cessation of the underlying cause."

45. Under Article 174, two new paragraphs, (2^1) and (2^2), are introduced after (2), which read as follows:

"(2^1) The management of the medical assistance granted in public hospitals can be transferred to local public administration authorities, accredited state medicine and pharmacy universities, through Government Decision, initiated by the Ministry of Health, as suggested by local public administration authorities, accredited state medicine and pharmacy universities, as required.

(2^2) The buildings where public hospitals mentioned under (2^1) perform their activity may be given for administration to local public administration authorities, accredited state universities for medicine and pharmacy, in accordance with the law."

46. Under Article 178 (2), point a) is amended as follows:

"a) on date of the signing of the contract, the respective person must be a graduate of postgraduate further education in management or health management, having lasted at least 3 months;".

47. Under Article 178, paragraph (3) is amended as follows:

"(3) The manager, physical or legal, signs management contracts with the Ministry of Health, ministries or institutions provided with their own healthcare network, represented by the Minister of Health, head of the ministry or institution, as required, for maximum 3 years. The management contract may cease before the deadline following annual assessment or whenever needed. Assessment is performed according to overall performance criteria established through Order of the Minister of Health, as well as according to specific criteria and averages established and approved through administrative action of the heads of ministries or institutions provided with their own healthcare network, of the head of the territorial-administrative unit, the Lord Mayor of Bucharest or the president of the county board, as required. When the mandate is suspended, the management contract may be prolonged over a 3-month period, maximum twice, period of organisation of the vacancy-filling contest, namely the public auction, as required. The minister of health, the representative minister or the mayor of the administrative-territorial unit, the mayor of Bucharest or the President of the county council, as required, issue an administration act assigning an interim manager until the manager job is filled, namely the organisation of the public auction, as required."

48. Under Article 179, paragraph (1) is amended as follows:

"ARTICLE 179

(1) The Administration Council organises a contest or public auction, as required, in order to select the manager/legal person able to ensure the management of the health unit, in accordance with the norms approved through Order of the Minister of Health or, as required, through Order of the Minister from ministries provided with their own healthcare network and through administrative act of the mayor of the administrative-territorial unit, the mayor of Bucharest or the President of the county council, the dean of the university of medicine and pharmacy, as required."

49. Under Article 186, paragraphs (3), (4) and (7) are amended as follows:

"(3) For public hospitals of the Ministry of Health, except for those mentioned under (2), members of the administration council are:

a) 3 representatives of the Ministry of Health or of county/Bucharest public health directorates;

b) a representative nominated by the county/local council, namely by the General Council of Bucharest;

c) a representative of the university/faculty of medicine, for clinical hospitals;

d) a representative of the territorial structure of the Romanian College of Physicians, as a guest;

e) a representative of the territorial structure of the Romanian Order of Medical Assistants, Nurses and Midwives, as a guest.
(4) The institutions mentioned under (2), (3) and (3^1) are also required to appoint alternates in the Administration Council.
.....
(7) The members of the Administration council of the public hospital are nominated through administrative act of the institutions mentioned under (2), (3) and (3^1)."
50. Under Article 186, a new paragraph, (3^1), is introduced after paragraph (3), which reads as follows:
"(3^1) In public hospitals belonging to the network of ministries and institutions provided with their own healthcare network, save those mentioned under (2), administration council members are:
a) 4 representatives of ministries and institutions provided with their own healthcare network for subordinated hospitals;
b) a representative of the faculty/university of medicine, for clinical hospitals;
c) a representative of the territorial structure of the Romanian College of Physicians, as a guest;
d) a representative of the territorial structure of the Romanian Order of Medical Assistants, Nurses and Midwives, as a guest."
51. Article 189^1 is amended as follows:
"ARTICLE 189^1
(1) Venues from public healthcare facilities in accordance with medical service agreements signed with health insurance houses can also be used for:
a) investments in the infrastructure;
b) provision with medical equipment.
(2) Expenses mentioned under (1) can be performed after having ensured operation expenses, in accordance with the provisions of Law no. 273/2006 on local public finances, as amended, Law no. 500/2002 on Public finances, as amended, as well as with compliance with provisions of Law no. 72/2013 on the measures for combating late payment of amounts resulting from agreements concluded between professionals and between professionals and contracting authorities."
52. On 1 August 2014, point a) of Article 190 (2) is repealed.
53. Under Article 190 (2), point c) is amended as follows:
"c) investments in the acquisition and building of new hospitals and for finalisation of pending projects;".
54. On 1 August 2014, point b) of Article 190 (3) is repealed.
55. Under Article 190^3, paragraph (2) is amended as follows:
"(2) Amounts required to perform the agreements mentioned under Article 190^1 e) are ensured from state budget funds and from personal revenues, through budget of the Ministry of Health."
56. Article 190^5 is amended as follows:
"ARTICLE 190^5
(1) Public hospitals from the network of local public administration authorities can be paid from state budget and from the revenues of the Ministry of Health, allocated through transfer based on contracts signed between special structures and local public administration authorities to whom the respective facilities subordinate, in accordance with the provisions of Article 34 (2) of Law no. 273/2006, as amended, for:
a) finalisation of new investment objectives, ongoing investments, investments financed, prior to the date of transfer of public hospital management, through yearly investment programs of the Ministry of Health;
b) supply with medical equipment;
c) major hospital rehabilitation;

d) financing of objectives in view of modernization, transformation and extension of existing buildings and of expertise, projection and reinforcement of buildings.
(2) Amounts allocated from the budget of the Ministry of Health mentioned under (1) b), c) and d), criteria for assignment, as well as the list of benefiting public hospitals are yearly approved through Government Decision, after publication of the state budget law.
(3) The decision mentioned under (2) is approved according to the proposals of special structures of the Ministry of Health following the requests of local public administration authorities."

57. Article 190^6 is amended as follows:

"ARTICLE 190^6
Local public authorities may participate in financing administration and operation expenses and staff expenses, established in accordance with the law, goods and services, investments, major rehabilitations, reinforcement, extension and modernisation, supply with medical equipment of transferred healthcare bed containing facilities, in accordance with the budget credits approved for this purpose from local budgets."

58. Under Article 198, paragraphs (1) and (3) are amended as follows:

"ARTICLE 198
(1) Financed hospitals based on agreements signed with health insurance houses must record, store, handle and forward legal information related to their activity, in accordance with the norms approved through Order of the Minister of Health and through Order of the NHIH president.
.....
(3) Non-compliance with the requirements mentioned under (1) are sanctioned according to the conditions mentioned in the Framework agreement approved through Government Decision."

59. Under Article 210, paragraph (1) is amended as follows:

"ARTICLE 210
(1) In line with this Title, the terms and notions used have the following meaning:
a) medical services – services included in client offerings, provided by physical and legal persons, in line with this Title;
b) suppliers – physical or legal persons authorised by the Ministry of Health to provide medical services, medicinal products and medical devices;
c) standard client offering – granted to insured persons; it includes medical services, healthcare services, medicinal products, healthcare materials, medical devices and other services to which insured persons are entitled and is approved through Government Decision;
d) minimal client offering – is granted to persons attesting their “insured person” status and includes healthcare services, medicinal products and healthcare materials only in case of medical-surgical emergencies and endemo-epidemic diseases, monitoring of the evolution of pregnancy and breastfeeding period, family planning services, preventive and care services provided by the community medical assistance and is approved through Government Decision;
e) authorisation – assessment of the competence and compliance with the legislation in the respective field, performed for all types of providers, needed in view of being granted permission to provide medical services in Romania;
f) assessment – external procedure for check-up of performances of a medical service provider attesting that the provider subject to this process corresponds to the standards established in advance in view of ensuring the provision of quality medical services;
g) contracting – process establishing the relationship between health insurance houses and providers within the social health insurance system;
h) reference price – price used in the social health insurance system for payment of medical services, medicinal products and medical devices, in accordance with the price policy of the Ministry of Health;

i) medical devices – used to improve sight, hearing, prosthesis, namely prostheses, orthoses, walking devices, needed in view of regaining certain organic or physiological deficiencies, as well as other types of devices mentioned in the framework agreement and in its Norms for enforcement;
j) co-payment – amount representing the payment of the insured person's quota, in accordance with the obligation mentioned under Article 219 g), in order to benefit from medical services included in the basic set of services, within the social health insurance system, according to the quantum and conditions established through framework agreement on conditions for grant of medical assistance within social health insurance system, in accordance with provisions of Article 217 (3) j);".

60. Article 211 is amended as follows:

"ARTICLE 211 (1) The following persons are considered insured persons, in accordance with the law:
a) all Romanian citizens residing in Romania who prove their contribution to the fund, in accordance with this law;
b) foreign citizens and stateless persons who have required and obtained the extension of the right of temporary stay or residence in Romania, who prove their contribution to the fund, in accordance with this law;
c) citizens from EU Member States, the European Economic Area and Swiss Confederation who do not own an insurance signed on the territory of another Member State having effects in Romania, who have required and obtained the right to reside in Romania for a 3-month period and who prove their contribution to the fund, in accordance with this law;
d) persons from EU Member States, the European Economic Area and Swiss Confederation meeting the requirements for a cross-border worker, namely performing a remunerated/free activity in Romania, residents of another Member State where they return on a daily or at least weekly basis who prove their contribution to the fund, in accordance with this law;
e) pensioners from the public pension system who do no longer reside in Romania, who establish their residence in an EU Member State, in a state belonging to the European Economic Area and Swiss Confederation, namely the residence of the territory of a state which has established a bilateral agreement on social security with provisions for the health-maternity insurance with Romania and prove the payment of the contribution to the fund, in line with this law.
(2) Insured persons are entitled to the standard client offering on beginning of payment of the contribution to the fund, and the remaining amounts are to be recovered by the National Agency for Fiscal Administration, in accordance with the law, including ancillary fiscal obligations due to fiscal claims.
(3) The ensured person status and the ensured rights stop:
a) for persons mentioned under (1) a), once they lose their right to reside in Romania, as well as in line with Article 258 (2);
b) for persons mentioned under (1) b), once they lose the right to reside in Romania, as well as in line with Article 258 (2);
c) for persons mentioned under (1) c), once they lose their right to reside in Romania, for more than a 3-month period, as well as in line with Article 258 (2);
d) for persons mentioned under (1) d), once they have lost their cross-border worker status, as well as in line with Article 258 (2);
e) for persons mentioned under (1) e), the insured person status and rights expire as of the date when pensioners from the Romanian public pension system are no longer required to pay the contribution to the fund, which is calculated from venues from the corresponding retirement pension in accordance with this system.
(4) The deduction of contributions to the fund for pensioners from the public pension system who do no longer reside in Romania and establish their residence in a Member State of the

European Union, a state of the European Economic Area or the Swiss Confederation, namely residence in a state having a bilateral agreement on social security with Romania, with specific provisions for disease-maternity insurance, is established through common agreement between the NHIH president and the president of the ‘National House for Public Pensions.
(5) Supporting documents on acquiring the status of “insured person” are established through Order of the NHIH president."

61. Under Article 213 (1), point d) is amended as follows:

"d) disabled persons who do not receive venues from work, pension or other sources, except for those obtained in line with Law no. 448/2006 regarding the protection and promotion of the rights of disabled persons, republished, as amended;"

62. Under Article 214, paragraph (2) is repealed.

63. Under Article 215, paragraph (3) is repealed.

64. Article 216 is repealed.

65. Article 217 is amended as follows:

"ARTICLE 217
(1) Insured persons are entitled to a standard client offering in accordance with this law.
(2) The rights mentioned under (1) are stablished based on a multiannual framework contract, elaborated by the NHIH following consultation with the Romanian College of Physicians, hereinafter RCP, the Romanian College of Dentists, hereinafter RCD, the Romanian College of Pharmacists, hereinafter RCP, the Romanian Order of Medical Assistants, Nurses and Midwives, hereinafter ROMANM, the Romanian Order of Healthcare Biochemists, Biologists and Chemists, hereinafter ROHBBC, as well as with representative patronal, syndical and professional organisations in the medical field. The project is approved by the Ministry of Health through Government Decision, within 60 days as of approval of the State Budget Law for the year awaiting approval of a new framework agreement.
(3) The framework agreement usually regulates the conditions for grant of medical assistance as regards:
a) standard client offering to which insured persons are entitled and the minimal client offering;
b) The list of medical services, healthcare services (at the patient’s residence as well), medicinal products, medical devices and other services for insured persons, pertaining to the standard client offering mentioned under a);
c) compliance with quality criteria for medical services granted in the context of client offerings;
d) the allocation of resources and control of the costs for social health insurance system in view of ensuring the financial balance of the fund;
e) the manners of payment used in contracting of the standard client offering, the method of discount and the documents required in this respect;
f) rehabilitation care at home;
g) conditions for grant of services at territorial level, as well as the list containing these services;
h) the prescription and release of medicinal products, health materials, medical devices;
i) manner of notification of the insured persons;
j) cofunding for certain medical services, as required.
(4) NHIH will elaborate the methodological norms for enforcement of the framework agreement, in collaboration with RCP, RCD, ROMANM, ROHBBC, RCP, as well as with representative patronal, syndical and professional organisations in the medical field, approved through Order of the Minister of Health and through Order of the NHIH president, within 30 days as of publication of the Government Decision mentioned under (2)."

66. Under Article 218, paragraph (1) is amended as follows:

"ARTICLE 218
(1) Insured persons benefit from the standard client offering in case of disease or accident, since the first day of illness or from the date of the accident until the date of healing, under the conditions established by this law, the framework agreement and its norms for enforcement."

67. Under Article 218 (2), point d) is amended as follows:

"d) to benefit from the standard client offering in a non-discriminating manner, in accordance with the law;".

68. Under Article 219, points g) and h) are amended as follows:

"g) to pay the contribution to the fund and the amount representing the co-payment/personal contribution, in accordance with the law;
h) to submit to medical service providers justifying documents attesting the "insured person" status, defined under Article 212 (1)."

69. Article 220 is amended as follows:

"ARTICLE 220
(1) Persons who are not insured benefit from medical services, within a minimal client offering, stipulated by this law.
(2) For persons having benefitted from medical services under the conditions of paragraph (1), providers of medical services are required to submit the identification data to the NHIH.
(3) The NHIH quarterly notifies the NAFA, according to a protocol, about the notification data of the persons mentioned under (2) in view of enforceability in accordance with the provisions of Law no. 571/2003 on the Romanian fiscal code, as amended, if venues requiring a social health insurance contribution are detected."

70. Article 222 is amended as follows:

"ARTICLE 222
Each insured person has the right to be informed at least once a year, through insurance houses, about the services to which he/she is entitled, rights and obligations."

71. Under Article 223, paragraph (1) is amended as follows:

"ARTICLE 223
(1) In order to prevent morbidity, to detect the illness in its incipient phase and to maintain health, insured persons will be informed ongoingly by health insurance houses about the means to preserve health, to decrease and avoid the grounds for morbidity and risks in case of drug, alcohol and cigarette consumption, directly or via the service provider having a contractual relationship with ensurance houses."

72. Paragraphs (2) and (3) of Article 223 are repealed.

73. Article 224 is repealed.

74. Article 225 is repealed.

75. Under Article 227, paragraphs (1) and (3) are amended as follows:

"ARTICLE 227
(1) Curative medical services whose costs are paid from the fund are:
a) emergency medical services other than directly financed by the Ministry of Health;
b) medical services granted to the patient until diagnosis of the illness: medical history, clinical examination, paraclinical investigation examinations;
c) medical, surgical treatment and some recovery procedures;
d) prescription of the treatment required for improvement or healing, as well as the indications for the living, working and hygienic-dietary regimen.
.....
(3) The particularisation of medical services mentioned under (1) and (2) and the manner of granting them are established through framework agreement and its norms for enforcement."

76. Under Article 228, (5) is amended as follows:

"(5) Medical care at home services, including palliative care at home, are granted by providers assessed and authorised in this respect."

77. Article 230 is amended as follows:
"ARTICLE 230
Insured persons benefit from dental treatments paid from the fund under the conditions established through framework agreement and through the norms for enforcement."
78. Article 233 is amended as follows:
"ARTICLE 233
(1) The countervalue of medicinal products prescribed for treatment of the illnesses of the categories of persons mentioned under Article 213 (1) a) and for pregnant and breastfeeding women are supported at reference price from the fund.
(2) The value of medicinal products mentioned under Article 232 (1), prescribed for treatment of the disorders encountered in the persons specified in the regulatory acts as shown under Article 213 (1) c) and d), are supported at reference price from the fund, according to the framework agreement and its norms for enforcement.
(3) Insured persons are entitled to healthcare materials and medical devices to improve sight, hearing, prostheses and other specialised devices, in view of prosthetic action upon certain organic/physiological deficiencies, for a determined/undetermined period of time, based on medical prescription, with or without personal contribution, under the conditions mentioned in framework agreement and in the norms for enforcement.
(4) Insured persons benefit from physiotherapeutic procedures, based on medical recommendation, with or without personal contribution, under the conditions mentioned in the framework agreement and its norms for enforcement.
(5) Insured persons benefit from medicinal products, health materials, medical devices and other therapeutic means specified in the methodological norms for enforcement of the framework agreement."
79. Under Article 234, paragraph (1) is amended as follows:
"ARTICLE 234
(1) Insured persons are entitled to receive some medical care at home, including palliative care at home, granted by a provider authorised and assessed in accordance with the law."
80. Article 235 is amended as follows:
"ARTICLE 235
Insured persons are entitled to health transportation, needed in view of performing medical services, in the cases mentioned in the framework agreement."
81. Under Article 237, paragraph (1) is amended as follows:
"ARTICLE 237
(1) Services which are not reimbursed from the fund by the facilities which have required them, whose countervalue is paid by the insured person, from the state budget or other sources, as required, are:
a) medical services granted for professional diseases, sport and workplace accidents, medical assistance at the workplace, medical assistance of athletes;
b) certain high-performance medical services;
c) certain dental assistance services;
d) high comfort hotel services;
e) plastic surgery performed on persons over 18 years old, except for breast reconstruction by prosthetics in case of oncological surgical interventions;
f) certain medicinal products, healthcare materials and manners of transportation;
g) the required medical services and the release of the medical documents required by the authorities which, on account of their activity, are entitled to know the health condition of the insured persons;
h) in vitro fertilisation;
i) medical assistance upon request;
j) the countervalue of certain materials required in view of improving sight and hearing;

k) personal contribution from the price of medicinal products, certain medical services and medical devices;
l) medical services required by the insured person;
m) certain services and rehabilitation procedures;
n) staff expenses for physicians and medical assistants, as well as expenses on medicinal products and healthcare materials in medical-social facilities;
o) services granted within sections/clinics for occupational diseases and occupational medicine cabinets;
p) hotel services required by patients whose affections are treated by day hospitalisation;
q) staff expenses for physicians, pharmacists and stomatologists during residency;
r) family planning services granted by the family practitioner within hospital planning cabinets;
s) staff expenses for physicians and health personnel from hospital facilities or sections treating dystrophia, neuropsychomotor recovery and rehabilitation or for children suffering from HIV/AIDS, reorganised in accordance with the law;
t) activities of particular interest in order to reach the objectives of the public health strategy, defined through framework agreement."

82. Under Article 237, a new paragraph, (1^1), is introduced after (1), which reads as follows:

"(1^1) For services undiscounted from the fund, required by army personnel and by wounded personnel of the Ministry of Internal Affairs, the person has become invalid or has acquired other physical or mental disorders during participation to military or military-related actions, the countervalue is ensured from the state budget, under the conditions established through Government Decision."

83. Under Article 237, paragraphs (2), (3) and (4) are amended as follows:

"(2) The services mentioned under (1) b), c), f) and m) and the personal contribution mentioned under paragraph (1) k) are established through framework agreement.
(3) Expenses for the activities mentioned under (1) q), r) and s) are supported from state budget.
(4) Expenses for the activities mentioned under (1) n) are ensured by transfers from state budget to local budgets, through budget of the Ministry of Health."

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

"c) supplier compliance with quality criteria elaborated by special structures and approved through Order of the Minister of Health, concerning services granted within packages of services."

85. Article 240 is repealed.

86. On 1 August 2014, Article 241 is repealed.

87. Article 242 is amended as follows:

"ARTICLE 242
Medicinal products granted by outpatient facilities within national healthcare programs are ensured through pharmacies belonging to health facilities where these are provided or through other pharmacies, as required."

88. Article 243 is repealed.

89. Article 244 is amended as follows:

"ARTICLE 244
(1) Providers of medical services, medicinal products, medical devices and medical and palliative care at home, meeting the assessment criteria established by the NHIH and the Ministry of Health, may enter a contractual relationship with health insurance houses.
(2) The assessment process involves medical cabinets, special outpatient facilities, hospitals, pharmacies, providers of medical and palliative care at home, providers of medical devices, private providers of emergency consultations at home and unassisted health transportation, as well as other physical or legal persons authorised in this respect by the Ministry of Health.

(3) The assessment of medical service providers, medicinal products, medical devices and medical and palliative care at home, which are on the verge of signing an agreement with insurance houses, is performed in accordance with the assessment methodology and criteria approved through Order of the Minister of Health and of the NHIH President.
(4) In view of performing the assessment process, providers of medical services, medicinal products, medical devices and medical and palliative care at home are required to pay an assessment tax whose quantum is approved through the Order mentioned under (3). Venues obtained after assessment activities become own revenues to the fund."

90. Under Article 246, paragraph (3) is amended as follows:

"(3) NHIH may establish direct contractual relationships with the providers of dialysis medical services, contractual relationships representing multiannual actions."

91. On 1 August 2014, points e) and g) of Article 252 (1) are repealed.

92. Article 254 is repealed.

93. Under Article 256, paragraph (2) is amended as follows:

"(2) The acquisition of contributions of legal and physical persons who are employers, and of required contributions owed to legal persons in order to become ensured persons is performed by the Ministry of Public Finances, through the National Agency for Fiscal Administration (NAFA) and its subordinated fiscal bodies, in accordance with the provisions of Government Ordinance no. 92/2003, republished, as amended."

94. Under Article 256, paragraph (3) is repealed.

95. Under Article 256, paragraph (5) is amended as follows:

"(5) The venues for which the contribution for vacations and allowances for social health insurance and the contribution quota are established are stipulated by Law no. 571/2003, as amended."

96. Under Article 258, paragraph (2) is amended as follows:

"(2) In case of non-compliance with the provisions of Article 257 (1) the provisions of Article 220 apply, 3 months after the last payment of the contribution."

97. Article 258^1 is repealed.

98. Under Article 259, paragraphs (4), (5) and (6) are repealed.

99. Under Article 259, paragraphs (9) and (10) are amended as follows:

"(9) Persons required to acquire the "insured person status", other than mentioned under (7) and Article 257, who do not benefit from health insurance without payment of the contribution, must pay a monthly contribution to social health insurance calculated through enforcement of the quota stipulated by Law no. 571/2003, as amended, to the country's gross basic salary.
(10) Foreigners entitled to certain forms of protection in accordance with Law no. 122/2006 on asylum in Romania, as amended, are required, in order to be granted the "insured person" status, to pay the social health insurance contribution as of date of receipt of the form of protection, in accordance with this law."

100. Under Article 259, paragraph (11) is repealed.

101. Under Article 260, paragraphs (2) - (4) are amended as follows:

"(2) The contributions for persons mentioned under Article 213 (2) d), f), i) and j) are established through enforcement of the quota stipulated by Law no. 571/2003, as amended, for the amount representing the value of two of the country's minimum gross basic salaries.
(3) Contributions for persons mentioned under Article 213 (2) b) and e) are established through enforcement of the quota stipulated by Law no. 571/2003, as amended, for the allowance for the inability to work due to an accident at work or to an occupational disease, namely upon unemployment benefit.
(4) Contributions for persons mentioned under Article 213 (2) g) are established through enforcement of the quota stipulated by Law no. 571/2003, as amended, upon the granted social aid, in accordance with the law, in order to ensure the guaranteed minimum income."

102. Under Article 261, (2) is repealed.

103. Under Article 261, (5) is amended as follows:
"(5) The persons mentioned under Article 257 and 258 are required to make available to fiscal bodies within the NAFA the justificatory and evidence documents needed in view of establishing liabilities to the fund."
104. Under Article 262, paragraph (1) is amended as follows:
"ARTICLE 262
(1) Amounts collected in accordance with Article 256 (2) are used:
a) to pay for medical services, medical products, health materials and medical devices, including services granted based on international documents with health provisions, Romania being a stakeholder;
b) a 3% quota for expenses for administration, functioning and capital of NHIH and health insurance houses. Surpassing the limit with 3% can be approved through yearly budget laws;
c) 1% of the reserve fund from the amounts yearly obtained at NHIH level, under the conditions mentioned under Article 256 (4^1)."
105. Under Article 262, paragraphs (1^1) and (1^2) are repealed.
106. After Article 262, a new Article, 262^1, is introduced, which reads as follows:
"ARTICLE 262^1
(1) The fund supports expenses in order to ensure the minimum package of services, except for community medical assistance and services for emergency medical assistance and qualified first aid mentioned under Article 90, Article 93 (1), (1^1), (4), (5) and (5^1).
(2) Expenses supported from the fund, mentioned under (1), are ensured through amounts transferred from the budget of the Ministry of Health, from state budget and own revenues, in accordance with the provisions of Article 256 (1) b) and d)."
107. Under Article 265, paragraph (2^1) is amended as follows:
"(2^1) Amounts allocated from state budget and own revenues of the Ministry of Health for set-up of national healthcare programs, which have not been used, are transferred by the NHIH into the account of the initial budget by the end of the year."
108. Under Article 268, paragraph (2) is amended as follows:
"(2) The members of expert commissions mentioned under (1) receive a monthly allowance of 1% of the allowance of the NHIH president, namely of the wage for the status of President/Director general of the health insurance house, granted in direct proportion with the number of actual participations to meetings. Travel allowances and expenses for participations to expert commissions are provided by the NHIH, namely by the health insurance house pertaining to the commission. The Regulation on organisation and operation and the duties of expert commissions are established through Order of the NHIH President."
109. Under Article 270 (1), point (n) is repealed.
110. Under Article 270, paragraph (1^1) is amended as follows:
"(1^1) NHIH organises and administers the Informatic Platform for health insurance, including: the single integrated information system, the national system of the social health insurance card, the national system for electronic prescription and the system of the patient's electronic health file, ensuring its interoperability with e-Health solutions at national level, in order to ensure the safe use of the information throughout the setup of health policies and for management of the health system."
111. Under Article 277, paragraph (2) is amended as follows:
"(2) The Administration Council has a Vice-president elected by the Administration Council by secret vote. The Vice-president of the Administration Council is also the Vice-president of the NHIH."
112. Under Article 295, a new paragraph, (3), is introduced after (2), which reads as follows:
"(3) When performing the attributions mentioned under (1), NHIH special structures cooperate with legal bodies and with other state institutions and authorities depending on the specific

field of competence."

113. Article 298 is amended as follows:

"ARTICLE 298

(1) NHIH, together with the RCP, RCD and RCP, organises the Central Arbitration Commission which can solve, upon request of one of the parties, issues between providers of medical services, medicinal products, medical devices and insurance houses. The Commission operates in junction with the NHIH and is an entity with no legal personality.

(2) The Central Arbitration Commission is made up of 6 mediators, of which 3 are appointed by the NHIH and one by each of the following: RCP, RCD and RCP. Under the same conditions, a substitute member will be elected for each moderator.

(3) The President of the central referral committee is a referee accepted by the parties."

114. Article 299 is amended as follows:

"ARTICLE 299

(1) The Regulation for organisation and operation of the Central referral commission is elaborated by the NHIH, in collaboration with RCP, RCD and RCP. The Regulation is approved through Government Decision at the proposal of the Ministry of Health.

(2) For activities performed within the Central Arbitration Commission, mediators benefit from a meeting allowance. The meeting allowance for mediators is 15% of the NHIH president allowance and 10% for the members of the technical secretariat.

(3) Expenses representing meeting allowances for mediators, as well as for the members of the technical secretariat are paid from the amounts allocated for fund administration."

115. Under Article 305, point a^1) is repealed.

116. Under Article 305, point d) is amended as follows:

"d) refusal to provide control authorities of ensurance houses with supporting documents and financial and accounting records on the amounts reimbursed from the fund, as well as medical and administrative documents of the controlled body, required for control."

117. Under Article 306, point b^1) is repealed.

118. Under Article 330, paragraph (2) is amended as follows:

"(2) The national social health insurance card is issued to prove the status of insured person for supply of certain medical services, and its performance and implementation is a public use project of national interest."

119. Under Article 331, three new paragraphs, (7) - (9), are introduced after (6), which read as follows:

"(7) Within storage media of the national card of social health insurance, in other partitions than those containing the data concerning the functionality of the health card, digital certificates may be registered, as defined by Law no. 455/2001 on the electronic signature, as amended, to be used in collaboration with Romanian public authorities; in such cases, using the card is regulated through regulatory acts elaborated or initiated by the concerned authorities.

(8) The new identity cards, released as of 2014, in several stages, containing adequate safety elements, in accordance with the provisions of Emergency Government Ordinance no. 82/2012 on amendment and supplementation of certain regulatory acts concerning the record of persons, identity documents of Romanian citizens, as well as the residence certificates of citizens from Member States of the European Union and of the European Economic Area residing in Romania, approved as amended through Law no. 235/2013, will also function as national social health insurance cards.

(9) When a citizen receives an identity card, as mentioned under paragraph (8), the national social health insurance card is no longer available."

120. Under Article 338^1, a new paragraph, (1), is introduced after (1^1), which reads as follows:

"(1^1) By exception from the provisions of Article 52 (10) of Law no. 500/2002, as amended, the Ministry of Health will not require interests, default fees or overdue interests to the

amounts representing prepayment granted in accordance with (1)."

121. Under Article 362, point b) is amended as follows:

"b) financing of national healthcare programs;"

122. Under Article 385, a new paragraph, (9), is introduced after (8), which reads as follows:

"(9) Physicians, public servants with a special status, are allowed to perform professional activities outside working hours, according to their abilities, in the public or private sector."

123. Under Article 466, a new paragraph, (1^2), is introduced after (1^1), which reads as follows:

"(1^2) The provisions of paragraph (1) also apply to physicians, public servants with a special status working in health facilities subordinated to ministries or central institutions provided with their own healthcare network, in accordance with the law, by waiver from the regime of incongruence applicable to this category of staff."

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

"17. *Public service obligation:* The obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question;".

125. Under Article 729, paragraphs (2) and (3) are amended as follows:

"(2) If the product ceases to be placed on the market of a Member State, either temporarily or permanently, the marketing authorisation holder shall notify the National Agency for Medicines and Medical Devices. Such notification shall, other than in exceptional circumstances, be made no less than 6 months before the interruption in the placing on the market of the product, whereas, in cases of discontinuation on the market for commercial reasons, such notification shall be made at least 12 months prior to interruption in the placing of the product on the market. During the 6 and 12-month interval, respectively, the marketing authorisation holder shall act in line with the competent authority of the reasons for such action in accordance with Article provisions of Article 792 (2) on insurance of adequate and ongoing supplies of medicinal products. The marketing authorisation holder shall notify the National Agency for Medicines and Medical Devices on the reasons for such action, in accordance with provisions of Article 840 (2).

(3) Upon request by the National Agency for Medicines and Medical Devices or of the Ministry of Health, as required, particularly in the context of pharmacovigilance, the marketing authorisation holder shall provide the National Agency for Medicines and Medical Devices with all data relating to the volume of sales of the medicinal product, and any data in his possession relating to the volume of prescriptions."

126. Article 739 is amended as follows:

"ARTICLE 739

(1) Before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation which appears necessary, the National Agency for Medicines and Medical Devices, Member States, the European Commission, the applicant or the marketing authorisation holder shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee for Medicinal Products for Human Use for application of the procedure laid down in Articles 32, 33 and 34 of Directive 2001/83/EC.

(2) Where the referral results from the evaluation of data relating to pharmacovigilance of an authorised medicinal product, the matter shall be referred to the Pharmacovigilance Risk Assessment Committee and Article 819^{10} (2) may be applied. The Pharmacovigilance Risk Assessment Committee shall issue a recommendation according to the procedure laid down in Article 32 of Directive 2001/83/CE. The final recommendation shall be forwarded to the Committee for Medicinal Products for Human Use or to the Coordination Group, as

appropriate, and the procedure laid down in 819^11 shall apply.
However, where one of the criteria listed in Article 819^9 (1) is met, the procedure laid down in Articles 819^9 - 819^11 shall apply.
The Member State concerned or the Commission shall clearly identify the question which is referred to the Committee for consideration and shall inform the applicant or the marketing authorisation holder.
If needed, The National Agency for Medicines and Medical Devices shall clearly identify the question which is referred to the Committee for Medicinal Products for Human Use for consideration and shall inform the applicant or the marketing authorisation holder.
(3) The National Agency for Medicines and Medical Devices and the applicant/marketing authorisation holder shall supply the Committee for Medicinal Products for human use with all available information referring to the matter in question.
(4) Where the referral application to the Committee for Medicinal Products for human use concerns range of medicinal products or a therapeutic class, the Agency may limit the procedure to certain specific parts of the authorisation; in that event, provisions Article 743 shall apply to those medicinal products only if they were covered by the authorisation procedures referred to in this section. Where the scope of the procedure initiated under this Article concerns a range of medicinal products or a therapeutic class, medicinal products authorised in accordance with Regulation (EC) No 726/2004, which belong to that range or class shall also be included in the procedure.
(5) Without prejudice to Article 739 (1), the National Agency for Medicines and Medical Devices may, where urgent action is necessary to protect public health at any stage of the procedure, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted; the National Agency for Medicines and Medical Devices shall inform the Commission, the European Medicines Agency and the other Member States, no later than the following working day, of the reasons for its action.
(6) Where the scope of the procedure initiated under this Article, as determined in accordance with paragraph (4), includes medicinal products authorised in accordance with Regulation (EC) No 726/2004, and where urgent action is necessary to protect public health, at any stage of the procedure, the National Agency for Medicines and Medical Devices shall apply action imposed by the European Commission for suspension of the marketing authorisations and prohibition of the use of the medicinal products concerned until a definitive decision is adopted by the European Commission."

127. Under Article 787, a new paragraph, (6), is introduced after paragraph (5), which reads as follows:

"(6) For medicinal products reimbursed in the frame of the national healthcare insurance system, the marketing authorisation holder or their representative in Romania shall take all measures required for wholesale distribution of these medicinal products through at least three authorised wholesale distributors, except for medicinal products supplied in accordance with provisions of Article 699."

128. Article 796^1 is amended as follows:

"ARTICLE 796^1
Provisions of Article 787 and Article 791 c) are not applicable for wholesale distribution of medicinal products to third countries and provisions of Article 791 b) and c^1 do not apply for direct transit by a medicinal product from a third country, without importation. However, in such case, wholesale distributors shall make sure that medicinal products are only obtained from persons authorised or entitled to provide medicinal products in accordance with legal provisions applicable in the concerned third country. For supply of medicinal products to persons from third countries, wholesale distributors shall make sure that the products are only supplied to persons authorised or entitled for reception of medicinal products for wholesale

distribution or to the public, in accordance with legal provisions applicable in the third country concerned. Provisions of Article 793 apply for supply of medicinal products to persons from third countries that are authorised or entitled to supply the public with medicinal products."

129. A new Article, Article 799^1, is introduced after Article 799, which reads as follows:

"ARTICLE 799^1

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

(2) The obligation mentioned under (1) is also applicable for beneficiaries of sponsoring, physicians, medical assistants, professional organisations, patient organisations and any other types of organisations in the healthcare system.

(3) The forms for declaration of sponsoring mentioned under (1) and (2) are approved through Order of the Minister of Health.

(4) Information in the forms mentioned under (3) are posted on the website of the NAMMD, for medicinal product advertising, of the Ministry of Health for medical devices and healthcare material, of the entity performing sponsorship activities, respectively, as well as of their beneficiaries, as required."

130. Article 819^9 is amended as follows:

"ARTICLE 819^9

(1) The National Agency for Medicines and Medical Devices, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, initiate the procedure provided for in this section by informing the other Member States, the European Medicines Agency and the Commission where:

(a) it considers suspending or revoking a marketing authorisation;

(b) it considers prohibiting the supply of a medicinal product;

(c) it considers refusing the renewal of a marketing authorisation; or

(d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, the holder has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or intends to take such action or has not applied for the renewal of a marketing authorisation.

(2) The National Agency for Medicines and Medical Devices, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, inform the other Member States, the European Medicines Agency and the Commission where it considers that a new contraindication, a reduction in the recommended dose or a restriction to the indications of a medicinal product is necessary. The information shall outline the action considered and the reasons therefore.

The National Agency for Medicines and Medical Devices shall, when urgent action is considered necessary, initiate the procedure provided for in this paragraph in any of the cases referred to under (1).

Where the procedure provided for in this section is not initiated, for medicinal products authorised in accordance with the procedures laid down in Chapter III of Title XVII, section 5, the case shall be brought to the attention of the Coordination Group.

Article 739 provisions shall be applicable where the interests of the Union are involved.

(3) Where the National Agency for Medicines and Medical Devices initiates the procedure provided for in this section and the medicinal product involved is authorised in more than one Member State, the former shall be informed by notification from the European Medicines Agency on outcome of verification of the safety concerns formulated and, respectively,

whether they relate to medicinal products other than the one covered by the information to the European Medicines Agency, or whether it is common to all products belonging to the same range or therapeutic class.
In such cases, procedures laid down in Articles 819^10 and 819^11shall apply. Otherwise, the safety concern shall be addressed by the National Agency for Medicines and Medical Devices. If needed, the National Agency for Medicines and Medical Devices shall make the information that the procedure has been initiated available to marketing authorisation holders.
(4) Without prejudice to the provisions of 819^9(1) and (2) and Articles 819^10 and 819^11, where urgent action is necessary to protect public health, the National Agency for Medicines and Medical Devices may suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted. The National Agency for Medicines and Medical Devices shall inform the European Commission, the European Medicines Agency and the other Member States no later than the following working day of the reasons for its action.
(5) At any stage of the procedure laid down in Articles 819^10-819^11, the European Commission may request Member States in which the medicinal product is authorised to take temporary measures immediately.
Where the scope of the procedure, as determined in accordance with paragraphs **(**1**)** and **(2)**, includes medicinal products authorised in accordance with Regulation (EC) No 726/2004, the European Commission may, at any stage of the procedure initiated under this section, take temporary measures immediately in relation to those marketing authorisations.
(6) The information referred to in this Article may relate to individual medicinal products or to a range of medicinal products or a therapeutic class.
If the European Medicines Agency identifies that the safety concern relates to more medicinal products than those which are covered by the information or that it is common to all medicinal products belonging to the same range or therapeutic class, it shall extend the scope of the procedure accordingly.
Where the scope of the procedure initiated under this Article concerns a range of medicinal products or therapeutic class, medicinal products authorised in accordance with Regulation (EC) No 726/2004**,** which belong to that range or class shall also be included in the procedure.
(7) At the time of the information referred to in paragraphs (1) and (2), the National Agency for Medicines and Medical Devices Member State shall make available to the European Medicines Agency all relevant scientific information that it has at its disposal and any assessment by the National Agency for Medicines and Medical Devices.”

131. Under Article 819^10, paragraph (1) is amended as follows:

"ARTICLE 819^10
(1) Following receipt of the information referred to in paragraphs (1) and (2) of Article 819^9, the National Agency for Medicines and Medical Devices shall publicly announce on its own website the initiation of the procedure in line with the public announcement of the by means of the European Medicines Agency on the European medicines web-portal.
The announcement shall specify the matter submitted to the Agency in accordance with Article 819^9, and the medicinal products and, where applicable, the active substances concerned. It shall also contain information on the right of the marketing authorisation holders, healthcare professionals and the public to submit to the European Medicines Agency information relevant to the procedure and it shall state how such information shall be submitted."

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

"m^1) fine between 50,000 and 100,000 lei, temporary (up to 6 months) suspension of the authorisation, for non-compliance with requirements mentioned under Article 695 (17) and Article 792 (2), as well as with requirements established in accordance with Article 792 (2^1)."

133. Under Article 836 (1), point n) is amended as follows:
"n) fine between 10,000 and 30,000 lei, for non-compliance with the obligation stipulated under Article 729 (2);".
134. Under Article 840, paragraphs (2) and (4) are amended as follows:
"(2) The marketing authorisation holder shall be obliged to forthwith notify the National Agency for Medicines and Medical Devices as well as competent authorities in other Member States concerned of any action taken by the holder to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. The marketing authorisation holder shall in particular declare if such action is based on any of the grounds set out in Article 828 or Article 829(1).”
.....
(4) Each year, the National Agency for Medicines and Medical Devices shall take account of the annual list published by the European Medicines Agency of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or which have been withdrawn from the market, including the reasons for such action."
135. Under Article 840, two new paragraphs, (2^1) and (2^2), are introduced after (2), which read as follows:
"(2^1) The marketing authorisation holder shall also make the notification pursuant to paragraph (2) of this Article in cases where the action is taken in a third country and where such action is based on any of the grounds set out in Article 828 or Article 829 (1).
(2^2) The marketing authorisation holder shall furthermore notify the European Medicines Agency where the action referred to in paragraph 2 or (2^1) of this Article is based on any of the grounds referred to in Article 828 or Article 829(1).”

*

Points 128 - 130 and 132 - 137 of this Emergency Ordinance transpose Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance, published in the Official Journal of the European Union, series L, no. 299 of 27 October 2012.
136. After Title XVII - "The medicinal product", two new Titles, Title XVIII "Cross-border medical assistance" and Title XIX "Medical devices", are introduced, which read as follows:

TITLE XVIII
Cross-border medical assistance

CHAPTER I
General provisions

ARTICLE 864
(1) This Title establishes the overall framework for the access to safe and quality cross-border medical assistance and promotes cooperation in the field of medical assistance between Romania and Member States of the European Union, hereinafter EU.
(2) This Title applies to medical assistance services granted to patients, irrespective of the manner of organisation, supply and financing of medical assistance services.
(3) This Title does not apply to:
a) prolonged caretaking services whose purpose is to provide assistance to persons requiring help to perform daily, routine tasks, as follows:

1. the treatment of patients requiring mandatory isolation or hospital admission and of persons devoid of freedom for which the court of justice has ruled the enforcement of a castigation in a prison hospital;
2. medical and palliative health care at home;
b) allocation of organs and access to organs in view of organ transplantation;
c) Except for Chapter V of this Title, vaccination programmes against contagious diseases, exclusively meant to safeguard population health and subject to specific measures of planning and implementation.
ARTICLE 865
(1) This Title is applied without prejudice to the legislation transposing the following regulations into European legislation:
a) approval of the Rules on determining the prices of medicinal products for human use, of the assessment criteria for medical technologies, of the documentation to be submitted by applicants, methodological tools used throughout the assessment process and assessment methodology on the inclusion, widening of indications or exclusion of medicinal products from the List of International Non-proprietary Names of medicinal products for insured persons, based on medical prescription, with or without personal contribution;
b) establishment of the conditions of introduction on the market and use of in-vitro, active implantable and plain medical devices;
c) person safety when dealing with personal data and free circulation of such data;
d) assignment of employees within performance of transnational services and free access to public information;
e) electronic commerce and certain measures to ensure transparency of public positions, prevention and sanctioning of corruption from the business background;
f) prevention and sanctioning of all forms of discrimination;
g) approval of the Norms on implementation of Good Clinical Practice rules for clinical trials performed on medicinal products for human use;
h) Title XVII - "The medicinal product", Article 695 - 862 of this Law;
i) organisation of blood transfusions, donation of blood and blood components of human origin and ensurance of their health quality and safety in view of therapeutic use;
j) approval of the standards on selection and assessment of the tissue and cells donor, alert systems and emergency procedures, qualification of the staff from tissue and cell banks, the quality system, the import and export of human tissues and cells, the relationships between tissue and cell banks and third parties, of the Methodological norms for enforcement of Title VI "Performance of sampling and transplantation of human organs, tissues and cells for therapeutic purpose" of Law no. 95/2006 on healthcare reform, as amended, and of Title VI "Performance of sampling and transplantation of human organs, tissues and cells for therapeutic purpose", Article 141 - 164 of Law no. 95/2006 on healthcare reform, as amended, on the Norms on set-up of the standard for professional training of the person assigned to ensure the quality of human tissues and/or cells, processed and/or used for therapeutic purpose and set-up of the National Transplant Agency;
k) the accreditation of diplomas and professional skills for regulated jobs available in Romania, nomination of the institution able to automatically recognize the documents attesting the skill acquired abroad, outside the learning system, by Romanian citizens or citizens of Member States of the European Union and of states from the European Economic Area, approval of the mandatory minimum criteria for authorisation and accreditation for higher education institutions in the following fields: medicine, dental medicine, pharmacy, medical assistants, midwives, veterinary medicine, architecture, as well as for the colleges for general medical assistants, for basic training, recognition of the veterinary skills and regulation of certain aspects concerning the performance of the “veterinary” job and of the diplomas and professional skills for regulated jobs in Romania, approval of the Process for Accreditation of

Qualification – professional training and experience – acquired in Romania, outside the national learning system, by Romanian citizens wishing to perform various activities, independently or as employees, on the territory of an EU Member State, concerning the qualification regimen for physicians, stomatologists, pharmacists, general medical assistants and midwives, acquired outside Romania, approval of the Methodology on the organisation and performance of the accommodation internship, aptitude test and establishment of the status of the persons mentioned under Article 40 - 42 of Government Decision no. 1.282/2007 approving the rules for the acknowledgment of diplomas, certificates and titles of doctors, dentists, pharmacists, general nurses and midwives, issued by a Member State of the European Union, a state of the European Economic Area or the Swiss Confederation, as amended, compliant with the countervailing measure in view of professional recognition in Romania, recognition of the veterinary qualification and regulation of certain aspects concerning the performance of the veterinary job; Title XII "Performance of the physician job. Organisation and operation of the Romanian College of Physicians", Article 370 - 467, Title XIII "Performance of the stomatologist job. The organisation and operation of the Romanian College of Stomatologists", Article 468 - 552, and Title XIV, "Performance of the pharmacist job. Organisation and operation of the Romanian College of Pharmacists", Article 553 - 641 of Law no. 95/2006 on healthcare reform, as amended; approval of the rules for the acknowledgment of diplomas, certificates and titles of doctors, dentists, pharmacists, general nurses and midwives, issued by a Member State of the European Union, a state of the European Economic Area or the Swiss Confederation; on the manner of performing a training through residency in the fields mentioned in the Index of medical, stomatological and pharmaceutical fields for the medical assistance network, as amended; approval of the Index of medical, dental and pharmaceutical fields for the medical assistance network, as amended; on organisation of the special human medical, stomatological and pharmaceutical postgraduate studies and human medical and pharmaceutical postgraduate studies; recognition of diplomas and professional skills for the regulated jobs in Romania; on performance of the job of general medical assistant, midwife and medical assistant, as well as the organisation and operation of the Romanian Order of Medical Assistants, Nurses and Midwives; organisation of judicial and extrajudicial technical expertise activities; the authorisation of criminologists who can be recommended by stakeholders and participate in performance of criminal expertises; organisation and performance of the “architect” job; approval of the Methodological norms on organisation and organisation and performance of the “architect” job; recognition of diplomas and professional skills for regulated jobs in Romania;

l) the amendment and supplementation of certain regulatory acts in the healthcare field.

(2) This Title does not bring prejudice to the duties of the Romanian state set up based on:

a) Regulation (EC) no. 859/2003 of the Council of 14 May 2003 extending the provisions of Regulation (EEC) no. 1408/71 and Regulation (EEC) no. 547/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality;

b) Regulation (EC) no. 726/2004;

c) Regulation (EC) no. 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and Regulation (EC) no. 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems;

d) Regulation (EC) no. 1.082/2006 of the European Parliament and of the Council of 5 July 2006 on European Grouping for Territorial Cooperation (EGTC);

e) Regulation (EC) no. 1.338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work;

f) Regulation (EC) no. 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I), Regulation (EC) no. 864/2007

of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II) and other Norms of the Union on private international law, particularly the norms pertaining to court jurisdiction and applicable legislation;
g) Regulation (EU) no. 1231/2010 of the European Parliament and of the Council of 24 November 2010 extending Regulation (EC) no. 883/2004 and Regulation (EC) no. 987/2009 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality.

CHAPTER II
Conceptual limitations

ARTICLE 866
In line with this Title, the terms and notions employed have the following significance:
a) medical assistance – healthcare services offered to patients by the medical staff for assessment, maintenance or recovery of their health condition, including the prescription, release and supply of medicinal products and medical devices;
b) insured person:
1. the persons and their family members, regulated by Article 2 of Regulation (EC) no. 883/2004, insured in line with Article 1 c) of this Regulation; and
2. nationals of third countries falling under the scope of Regulation (EC) no. 859/2003 or Regulation (EU) no. 1.231/2010 or who meet the conditions of the legislation of the Member State of affiliation for the right to perform;
c) Member State of affiliation:
1. for persons mentioned under b) (1), Romania or another EU Member State enabled to grant the insured person a preliminary authorisation to receive adequate treatment outside the Member State of residence in accordance with Regulation (EC) no. 883/2004 and Regulation (EC) no. 987/2009;
2. for persons mentioned under b) (2), Romania or another EU Member State enabled to grant the insured person a preliminary authorisation to receive adequate treatment in another Member State in accordance with Regulation (EC) no. 859/2003 or with Regulation (EU) no. 1.231/2010. If no EU Member State is authorised in accordance with these Regulations, the Member State of affiliation is the Member State in which the person has acquired the "insured person" status, where he/she is entitled to a workmen's compensation insurance in accordance with the legislation of the respective Member State;
d) Member State in which the treatment is performed – Romania or another EU Member State where the patients receives medical assistance. As far as telemedicine is concerned, medical assistance is considered to be provided in Romania or another EU Member State where the medical service provider is assigned;
e) cross-border medical assistance - medical assistance provided or prescribed in an EU Member State other than the Member State of affiliation;
f) healthcare professional – physician, stomatologist, pharmacist, nurse responsible for general care, medical assistant and midwife in accordance with Article 642 or someone considered healthcare professional in accordance with the legislation of the Member State where the treatment is performed;
g) medical service provider – any physical/legal person who legally provides medical assistance in Romania or another Member State;
h) patient – any physical person requiring or receiving medical assistance in Romania or another EU Member State;
i) medicinal product – in accordance with the definition mentioned under Article 695 (1);
j) medical device – in accordance with the definition mentioned under Article 2 1 of Government Decision no. 798/2003 on the establishment of requirements for placing on the market and use of in vitro-diagnostic devices, as amended; Article 2 (1) 1 of Government

Decision no. 54/2009 on the conditions for the entry of medical devices on the market and in accordance with the provisions of Article 2 (1) of Government Decision no. 55/2009 on active implantable medical devices;
k) prescription – prescription of a medicinal product/medical device released by a person qualified in this respect in Romania or in the Member State where the prescription is released;
l) medical technology – a medicinal product, a medical device or medical and surgical procedures, as well as measures for prevention, diagnostic or treatment of diseases, used in the field of medical assistance;
m) medical records – set of documents containing any type of data, assessments and information concerning the condition and clinical evolution of a patient during treatment;
n) Internal Market Information System – the electronic platform mentioned by Regulation (EU) no. 1024/2012 of the European Parliament and of the Council of 25 October 2012 on administrative cooperation through the Internal Market Information System and repealing Commission Decision 2008/49/EC of the Commission («the IMI Regulation»).

CHAPTER III
Responsibilities when granting cross-border medical assistance

ARTICLE 867
In line with this Title, cross-border medical assistance is granted in Romania by adoption of the principle of universality, access to quality care, equity and solidarity and in accordance with:
a) National legislation concerning medical assistance;
b) National standards and directions concerning quality and safety mentioned in the Rules on conditions to be met by a hospital in view of obtaining an operating permit, as amended, in the clinical guidelines and protocols approved through Order of the Minister of Health, as well as in accordance with the accreditation standards defined by the National Commitment for Hospital Accreditation, as well as in other legal provisions in force;
c) EU legislation concerning safety standards.
ARTICLE 868
(1) Apart from the National Health Insurance House, hereinafter NHIH, the National Contact Point, hereinafter NCP, is set up and operates as a non-juridical structure, having the following attributions:
a) Consultations with patient organisations, special structures of the Ministry of Health, providers of medical services and health insurers;
b) Collaboration with other NCPs and with the European Commission in this respect;
c) Provision to patients, upon request, of contact data of national contact points from other EU Member States;
d) Provision to patients of information about providers of medical services, including information upon request concerning a specific right of providers to perform services or any constraints in performing their professional activity, in accordance with Article 871, as well as information related to patient rights, procedures referring to complaints and mechanisms for damage repair, in accordance with legal provisions in force, as well as legal and administrative options available in order to solve litigations, also in case of a prejudice due to cross-border medical assistance;
e) Provision to patients and medical staff, upon request, of information concerning the rights for benefitting from cross-border medical assistance, the terms and conditions for reimbursement of costs and procedures for assessment and establishment of the respective rights. The information concerning cross-border medical assistance make a clear distinction between patient rights in line with this Chapter and those resulting from Regulation (EC) no. 883/2004.

(2) The information mentioned under (1) are easily accessible and made available via electronic means and in formats accessible for disabled persons, as required.
(3) Non-compliance with the attributions mentioned under (1) by NCP staff represents a disciplinary offence and is punishable by in accordance with the law.
ARTICLE 869
(1) The organisation and operation of the NCP are established through common Order of the Minister of Health and of the President of the National Health Insurance House.
(2) Financing of the NCP is ensured from the single national fund for social health insurance.
ARTICLE 870
(1) The Ministry of Health notifies the European Commission about the name and contact data of the assigned NCP.
(2) The Ministry of Health publishes on its website the information mentioned under (1) and monitors the fulfilment of NCP's attributions in accordance with the norms approved through Government Decision.
ARTICLE 871
It is NCP's duty to provide patients, upon request, in accordance with the law, information concerning:
a) the standards and guidance mentioned under Article 867 b);
b) the surveillance and assessment of medical service providers;
c) providers of medical services falling under the scope of the standards and directions mentioned under point a);
d) hospital accessibility for disabled persons.
ARTICLE 872
(1) Patients are entitled to submit complaints in order to fix the damages in accordance with the legal provisions in force, if they suffer from prejudice issued from the medical assistance they received.
(2) Patients are entitled to the protection of their private life as regards the handling of personal data, in accordance with Law no. 677/2001 on the protection of individuals with regard to the processing of personal data and the free movement of such data, as amended, Law no. 506/2004 on the processing of personal data and protection of privacy in the electronic communications, as amended, and Article 21 of Law no. 46/2003 on patients' rights.
(3) In order to ensure the continuity of medical assistance, patients in other EU Member States having benefitted from treatment in Romania, are entitled to the medical dossier of the respective treatment, on paper or in electronic format, and are entitled to at least one copy of this dossier, in line with the provisions of Law no. 677/2001, as amended, in accordance with the norms approved through Government Decision.
(4) Romanian patients wishing to benefit or benefitting from cross-border medical assistance have distant access, in accordance with the law, to their medical files, or at least they receive a copy of these, in accordance with and subject to provisions of Law no. 677/2001, as amended, Ombudsman's Order no. 75/2002, Law no. 46/2003, Law no. 506/2004, as amended and Law no. 102/2005, as amended, in accordance with the norms approved through Government Decision.
(5) Insured persons are entitled to reimbursement of the counter value of cross-border medical assistance irrespective of the EU site where medical assistance has been granted.
ARTICLE 873
(1) Providers of medical services performing their activity in Romania have the following responsibilities:
a) to make available to patients information about treatment options, availability, quality and safety of medical assistance provided in Romania;
b) to make available to patients accurate invoices and information concerning prices and/or tariffs;

c) to make available to patients information on authorisation/registration, to assign them as insured persons or concerning other means of personal/collective protection concerning civil liability of the medical staff and of the medical service provider, in accordance with legal provisions;
d) to grant cross-border medical assistance without discrimination due to nationality grounds to all patients in the other EU Member States, except for cases in which this is justified by compulsory grounds of general interest, such as requirements for planning in view of ensuring sufficient and permanent access to a wide area of quality treatments in order to keep costs under control and to avoid, as much as possible, any waste of financial, technical and human resources, to take measures on the access to the treatments meant to fulfil their main responsibility to ensure sufficient and permanent access to medical assistance; exceptional cases defined by this paragraph are established through Government Decision;
e) to require from patients residing in other EU Member States the same prices and/or tariffs as those required from Romanian citizens in similar medical conditions. If there are no similar prices and/or tariffs for natives, prices and/or tariffs are calculated by providers in accordance with objective undiscriminating criteria;
f) to perform medical monitoring if a patient has benefitted from cross-border medical assistance, similar with the medical assistance the patient would have received in Romania, if such monitoring proves useful;
g) to respect the privacy of personal data in accordance with legal provisions in the field;
h) to make available to patients the documents mentioned under Article 872 (3) and (4) within 5 working days as of record of the application.
(2) Providers of medical services make freely available to NCP, upon request, the information mentioned under (1) a), b) and c).
(3) Non-compliance with the requirements mentioned under (1) represents a contravention and is punishable by from 500 to 5.000 lei.
(4) Provisions referring to contraventions in this Law are supplemented with the provisions of Government Ordinance no. 2/2001, approved as amended through Law no. 180/2002, as amended.
(5) Fines are periodically updated through Government Decision.
(6) Contravention acknowledgement and sanction enforcement are performed by the assigned staff and are fined by control bodies of the Ministry of Health, the Ministry of Public Finance, the National Authority for Consumer Protection, in accordance with legal jurisdictions.

CHAPTER IV
Cost reimbursement

ARTICLE 874
(1) Cross-border medical assistance costs are reimbursed by health insurance houses in accordance with the provisions of this Title.
(2) Without prejudice to the provisions of Regulation (EC) no. 883/2004, insured persons belonging to the mandatory health insurance system of Romania, who travel to another EU Member State in order to benefit from cross-border medical assistance, must pay the countervalue of medical services, medicinal products and medical devices received in accordance with the legislation of the Member State where medical assistance is granted.
(3) The countervalue of medical services, medicinal products and medical devices mentioned under (1) will be reimbursed by the health insurance house to which the insured person belongs:
a) if medical services, medicinal products and medical devices are found among the services to which the ensured person is entitled to in accordance with the legislation for social health insurance and are reimbursed from the Single National Fund of Social Health Insurance;

b) if the eligibility criteria mentioned in the methodological norms approved through Government Decision are met;
c) up to the level of prices/tariffs which would have been supported by Romania through the social health insurance system, if the respective medical assistance would have been granted in Romania, without exceeding the effective prices/tariffs of medical assistance received, as shown in payment documents and without supporting the countervalue of lodging and travelling services supported by insured persons, as well as additional costs supported by disabled persons due to one or several disabilities when benefitting from cross-border medical assistance.
(4) The methodology for reimbursement of prices/tariffs representing the countervalue of cross-border medical assistance, as well as their level, is established through Government Decision.
ARTICLE 875
(1) If county health insurance houses, the health insurance house of Bucharest and the Health Insurance House of Defence, Public Order, National Safety and Legal Authority, hereinafter health insurance houses, do not approve insurers' applications for reimbursement of the countervalue of cross-border medical assistance, these are required to notify this fact in writing, stating the legal ground, in accordance with the deadline specified in the methodological norms approved through Government Decision.
(2) Insured persons may make an appeal against the situation specified under paragraph (1) or against the countervalue of reimbursed cross-border medical assistance to the health insurance house to which the insured person belongs in accordance with Law 554/2004 on administrative litigations, as amended.
(3) Following response to the appeal or to expiry of the deadline, the insured person may contact the administrative court in accordance with the provisions of Law no. 554/2004, as amended.

CHAPTER V
Medical assistance subject to preliminary authorisation

ARTICLE 876
(1) Medical assistance subject to prior authorisation is limited to medical assistance which:
a) is subject to planning requirements for ensurance of sufficient and permanent access to a balanced set of quality treatments in Romania or wishes to control costs and to avoid, as much as possible, any waste of financial, technical and human resources and:
(i) includes the patient's hospitalisation for continual hospitalisation – for more than one day – for the types of treatment established through Government Decision;
(ii) requires the use of an infrastructure or of an extremely performant and costly medical equipment;
b) involves treatments posing risk for the patient/population;
c) is provided by a medical service provider who, on a case-by-case basis, could engender serious and specific healthcare safety or quality concerns, except for medical assistance compliant with Union legislation ensuring a minimum level of safety and security in the EU.
(2) Medical assistance subject to prior authorisation, the conditions for authorisation and deadline for submission of a reply to marketing authorisation applications are established through Government Decision.
(3) As regards the applications for preliminary authorisation submitted by an insured person in order to benefit from cross-border medical assistance, health insurance houses assess compliance with the conditions mentioned in Regulation (EC) no. 883/2004. If the conditions are met, prior authorisation is granted based on the respective regulation, unless the insured person requires otherwise, in written form.

(4) The Ministry of Health notifies the European Commission about the categories of medical assistance subject to prior authorisation.

ARTICLE 877

(1) If health insurance houses do not approve insurers' applications for reimbursement of the countervalue of cross-border medical assistance, they are required to notify this fact in writing, stating the legal ground, in accordance with the deadline specified in the methodological norms approved through Government Decision.

(2) Insured persons may make an appeal concerning the situation mentioned under paragraph (1) to the health insurance house to which the insured person belongs within 15 days as of the date of notification, which awaits an answer within 15 days as of record of the appeal.

(3) Following the answer to the appeal or to expiry of the deadline mentioned under paragraph (2), the insured person may contact the administrative court in line with provisions of Law no. 554/2004, as amended.

CHAPTER VI
Cooperation for medical assistance

ARTICLE 878

(1) In view of enforcing this Title, the Ministry of Health cooperates with similar structures in the other Member States by exchanging information, particularly between their NCPs, in accordance with Article 868 (1) b).

(2) The Ministry of Health enables, according to its abilities, cooperation in view of grant of cross-border medical assistance at national/territorial and local level, also through information and communication technology and other forms of cross-border cooperation.

ARTICLE 879

(1) As coordinator of the Internal Market Information System (IMIS), the College of Physicians, the College of Dental Surgeons, the College of Pharmacists and the Order of Nurses, Midwives and Medical Assistants, as competent authorities in line with Regulation (EU) no. 1.024/2012, the Ministry of Health makes available to NCPs and authorities in other Member States, freely and upon request, information concerning the practice license of the assessed medical staff, in view of granting cross-border medical assistance.

(2) The exchange of information with the authorities in other Member States is performed via the Internal Market Information System.

ARTICLE 880

(1) If a medicinal product is authorised for the Romanian market and included on the List of medicinal products for insured persons, in accordance with Title XVII – The medicinal product or with Regulation (EC) no. 726/2004, the prescriptions released to a patient in another EU Member State for such product can be used in Romania in accordance with the legislation in force and any restrictions related to the recognition of individual prescriptions are forbidden, unless these prescriptions:

a) stick to what is necessary and proportionate to protect human health and are undiscriminating; or

b) are based upon legitimate and rightful doubts related to the authenticity, content or accuracy of an individual prescription.

(2) The recognition of prescriptions mentioned under (1) does not bring prejudice to national regulations for release of prescription and medicinal products, including generic or any other type of substitution. The recognition of prescriptions does not bring prejudice to the norms concerning medicinal product reimbursement. The reimbursement of the cost of medicinal products is established through methodological norms approved through Government Decision.

(3) Prescription recognition does not bring prejudice to the pharmacist right, in accordance with the legislation in force, to reject, due to ethical reasons, the release of a medicinal product subject to a prescription released in another EU Member State, if the pharmacist would be entitled to refuse the release, in case the prescription would have been released in the Member State of affiliation.
(4) Apart from prescription recognition, if a prescription is issued in the Member State where the treatment is performed for products or medical equipment available in Romania and prescription release is required in Romania, continuity of treatment will be ensured in accordance with the methodological norms approved through Government Decision mentioned under (2).
(5) This Article also applies to medical devices legally introduced on the Romanian market and discounted by the health insurance system.
(6) The provisions of (1) do not apply to medicinal products subject to a special medical prescription, as shown under Article 781 (2).

CHAPTER VII
Reference European networks

ARTICLE 881
The Ministry of Health supports the development of reference European networks through:
a) connection of medical service providers and adequate expertise centres on national territory and ensurance of information spread towards providers of medical services and adequate expertise centres on national territory;
b) encouragement of participation of medical service providers and expertise centres to reference European networks.

CHAPTER VIII
Rare diseases

ARTICLE 882
The Ministry of Health cooperates with the other EU Member States as regards the development of the ability of diagnostic and treatment through:
a) enhancing the degree of information of medical staff concerning EU available instruments, in order to provide assistance for correct diagnosis of the rare disease, particularly the Orphanet database, and for reference European networks;
b) enhancing the degree of information of patients, medical staff and bodies responsible for financing medical assistance concerning the possibilities provided by Regulation (EC) no. 883/2004 to send patients who suffer from rare diseases in other Member States even for being granted diagnostic and treatments unavailable in the affiliated Member State.

CHAPTER IX
e-Health

ARTICLE 883
The Ministry of Health and the National Health Insurance House cooperates and participates to exchanges of information with other EU Member States operating within a voluntary network which connects e-health national authorities assigned by EU Member States.

CHAPTER X
Cooperation concerning assessment of medical technology

ARTICLE 884
(1) The Ministry of Health participates to the meetings and activities of the EU voluntary network which connects national authorities and bodies responsible for assessment of health technologies.
(2) The Ministry of Health informs the European Commission about the contact data of assigned representatives.

CHAPTER XI
Final provisions

ARTICLE 885
(1) The Ministry of Health provides the European Commission with assistance and all information available in view of performing implementation assessments and reports.
(2) NHIH appeals to the Administration Commission set up based on Article 71 of Regulation (EC) no. 883/2004 on approaching financial consequences of enforcement of this Title in EU Member States which have chosen reimbursement based on fixed amounts, in the cases regulated by Article 20 (4) and Article 27 (5) of the respective Regulation.

*

This Title partially transposes Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, published in the Official Journal of the European Union, series L, no. 88 of 4 April 2011, p. 45 - 65.

TITLE XIX
Medical devices

CHAPTER I
General provisions

ARTICLE 886
(1) This Title establishes the legal and institutional framework for control of commissioned and in-use medical devices, as well as for the control of marketing, distribution and supply of services in the field of medical devices.
(2) Provisions of this Title are also applicable to accessories of medical devices, when used together with a medical device to allow its use for the intended purpose. In line with this Title, accessories are considered medical devices.
ARTICLE 887
(1) The terms used in this Title are defined in accordance with provisions of Article 2 of Government Ordinance no. 20/2010 on establishing certain measures for approximated implementation of EU legislation harmonising product marketing conditions, as published in the Official Gazette of Romania, Part I, no. 606 of 26 August 2010, as amended, Article 2 of Government Decision no. 54/2009 regarding conditions for the placing on the market of medical devices, published in the Official Gazette of Romania, Part I, no. 94 of 17 February 2009, Article 2 of Government Decision no. 55/2009 on active implantable medical devices, published in the Official Gazette of Romania, Part I, no. 112 of 25 February 2009, and of Article 2 of Government Decision no. 798/2003 on establishment of requirements on placing on the market and use of in-vitro diagnostic devices, published in the Official Gazette of Romania, Part I, no. 555 of 1 August 2003, as amended.

(2) In line with this law, the phrase “surveillance in use” is defined as the set of measures ensuring and confirming the safe use and performances, in accordance with the intended goal, throughout the entire period of utilization of the medical device; incidents in use are identified.
(3) In line with this Title, a specialised structure is a public institution subordinated to the Ministry of Health, with specific attributions in the field of medical devices.

ARTICLE 888

(1) Activities related to the marketing, distribution and supply of services in the field of medical devices are performed in accordance with provisions of this Title and of methodological rules, approved through administrative action of the manager of the specialised structure.
(2) The activities mentioned under (1) are submitted for control through approval. Activities performed by the manufacturer of medical devices himself subject to these activities are the exceptions to application of this requirement.
(3) The approval mentioned under (2) is granted by a specialised structure, in accordance with applicable methodological rules, based on assessment of the expertise and ability of natural or legal persons, as required, to perform activities requiring approval.

ARTICLE 889

(1) Medical devices are marketed, distributed, installed and maintained for use in accordance with the proposed scope, only by physical or legal persons for which the approval mentioned under Article 888(3) has been issued.
(2) Provisions of (1) do not apply to natural and legal persons legally performing activities such as marketing, distribution, commissioning and maintenance of medical devices in their EU or EEA state of origin.
(3) Natural and legal persons residing in Romania, performing activities mentioned under Article 888 (1) are required, prior to performing the respective activities, to apply for approval mentioned under Article 888 (3).
(4) Natural and legal persons granted approval, mentioned under Article 888 (3), are required to notify the specialised structure about any change brought to the conditions under which the approval has been granted.
(5) Physical and legal persons performing activities mentioned under Article 888 (1) who change the functional parameters or the configuration of medical devices are considered manufacturers and are required, prior to commissioning and use of the modified medical devices, to submit them for assessment of compliance, in accordance with applicable legal requirements.

ARTICLE 890

Commissioned and in-use medical devices shall comply, according to the terms established through the instructions approved through administrative action of the head of the specialised structure, with the following manners of control:
a) periodic check-up;
b) unannounced inspection and testing;
c) surveillance in use.

ARTICLE 891

Assessment activities mentioned under Article 888 (3) and control activities stipulated under Article 890 are performed by a specialised structure.

ARTICLE 892

(1) In line with the provisions of this Title, the specialised structure has the following main duties:
a) to elaborate specific technical procedures for medical devices, approved through administrative act of its manager;
b) to assess and/or audit, upon request, physical or legal persons requiring approval as mentioned under Article 888 (3);

c) to ensure, by examination and testing, the control of medical devices in use, in accordance with methodological norms approved through administrative action of the manager;
d) to ensure assessment of the performances of medical devices, under the conditions mentioned in this Title;
e) periodically informs the Ministry of Health about activities conducted in the respective field of competence.
(2) The specialised structure performs other activities as well, in accordance with the law.
ARTICLE 893
(1) Second-hand medical devices, provided free of charge or purchased, shall be marketed, commissioned and used only after assessment by a specialised structure and based on the approval granted.
(2) Second-hand medical devices mentioned under (1), marketed and/or commissioned, shall be labelled with the EC marking and their compliance shall have been assessed prior to placement on the market, in accordance with European rules on medical devices.

CHAPTER II
Competent authority for medical devices

ARTICLE 894
(1) the specialised structure is the competent, decision-making authority for medical devices.
(2) the specialised structure performs the duties of a competent authority, as mentioned in the legislation, and proposes the Minister of Health regulatory acts for transposition of European directives or implementation of the legal framework of EU regulations in the field of medical devices, as required.

CHAPTER III
Surveillance of medical devices in use

ARTICLE 895
To ensure appropriate safety and performance suitable to the intended purpose of the medical device and to avoid incidents, users are required:
a) to use medical devices only for their intended purpose;
b) to ascertain that medical devices are used during their period of validity only, when required, and that no deviations exist from operational performances and applicable safety requirements;
c) to enforce a program for surveillance of medical devices, taking into account the risk posed to the patient, their intended use and complexity, in accordance with the methodological rules in force;
d) to ensure periodic check-up, maintenance and repair of medical devices in collaboration with facilities specialised in delivery of such services;
e) to notify manufacturers and specialised structures about any incident during use;
f) to report to the specialised structure all medical devices in the unit, recorded in the accounting records as fixed assets, irrespective of the manner of their acquisition, in accordance with the methodological rules approved through order of the head of the specialised structure;
g) to ensure a documented inventory system for medical devices in use, repaired and checked, in accordance with the methodological rules in force.

CHAPTER IV
Penalties

ARTICLE 896
Non-compliance with provisions of this Title results in disciplinary, material, civil or criminal liability, as required, in accordance with the law.
ARTICLE 897
The following are considered offences and shall be punishable as follows:
a) non-compliance with provisions of Article 889 (1) is punishable by fine from 5,000 to 10,000 lei, applicable to the provider of the unauthorised activity;
b) non-compliance with provisions of Article 889 (5) is punishable by fine from 10,000 to 15,000 lei and withdrawal of the authorisation mentioned under Article 888 (3);
c) non-compliance with provisions of Article 893 is punishable by fine from 5,000 to 10,000 lei, applicable to the provider and the healthcare unit, and prohibition to use the medical device until grant of the approval specified in this Title;
d) non-compliance with provisions of Article 889 (4) is punishable by fine from 2,000 to 5,000 lei;
e) non-compliance with provisions of Article 895 a) - e) is punishable by fine from 5,000 to 10,000 lei;
f) non-compliance with provisions of Article 895 f), punishable by fine between 2.000 and 5.000 lei;
g) any type of illegal obstruction of the persons entitled to perform the attributions mentioned in this Title, is punishable by fine from 5,000 to 10,000 lei.
ARTICLE 898
Note of contraventions and enforcement of civil fines are performed by staff of the specialised structure, assigned in this respect.

CHAPTER V
Database

ARTICLE 899
Data recorded in accordance with this Title are stored into a database organised and coordinated by a specialised structure.
ARTICLE 900
The methodological rules and instructions approved through order of the head of the specialised structure in accordance with provisions of this law are to be published.

CHAPTER VI
Transitory and final provisions

ARTICLE 901
(1) To grant the approval mentioned under Article 888 (3), the specialised structure shall require a fee established through Government Decision.
(2) As regards examinations mentioned under Article 892 (1) b) - d), the specialised structure establishes and collects the amounts of fee-based services, established through Order of the Minister of Health.
ARTICLE 902
Legal and natural persons pertaining to the provisions of this Title are required to ensure the confidentiality of information issued when performing work tasks.

ARTICLE 903
Within 3 months as of entry into force of this Title, the specialised structure shall issue the methodological implementation rules, as approved through Order of the Minister of Health."

137. Throughout the law, "public health control" is replaced with "public health inspection".

ARTICLE II
(1) Within 90 days as of entry into force of this Emergency Ordinance, the National Agency for Medicines and Medical Devices is reorganised by division into the National Medicines Agency and the National Agency for Acquisitions, Medical Devices and Investment in Healthcare, through Government Decision, in accordance with the law.
(2) The attributions in the field of medical devices, the staff and heritage pertaining to medical devices structures shall be taken over by the National Agency for Acquisitions, Medical Devices and Investment in Healthcare.
(3) The payment categories for, as mentioned under paragraph (2), shall be made with maintenance of salary entitlements and the status of each category of staff.
(4) The National Agency for Acquisitions, Medical Devices and Investment in Healthcare assumes the heritage of medical devices structures mentioned under (1), based on the financial situations set up in accordance with Article 28 (1) of Accounting Law no. 82/1991, republished, as amended, and through delivery-receipt protocol.
ARTICLE III
(1) Within 90 days as entry into force of this Emergency Ordinance, the National Public Health Institute is reorganised, through Government Decision, by partial division and taking over the activity, personnel and heritage of the National Centre for Organisation and Ensurance of the Informational and Informatic System in the Healthcare Field by the National Agency for Acquisitions, Medical Devices and Investment in Healthcare.
(2) The staff of the National Centre for Organisation and Ensurance of the Informational and Informatic System in the Healthcare Field mentioned under (1) is taken while maintaining salary entitlements and the status of each staff category.
(3) The National Agency for Acquisitions, Medical Devices and Investment in Healthcare assumes the heritage of the National Centre for Organisation and Ensurance of the Informational and Informatic System in the Healthcare Field, established under the financial circumstances set up in accordance with Article 28 (1) of Law no. 82/1991, republished, as amended.
ARTICLE IV
(1) Within 90 days as of entry into force of this Emergency Ordinance, through Government Decision, the National School of Public Health, Management and Professional Development of Bucharest is reorganised through partial division; the Ministry of Health and its special structures undertake some of its activities.
(2) The National School of Public Health, Management and Professional Development of Bucharest also performs activities of training and professional development of healthcare staff in the field of management of projects from European or structural funds.
(3) The Ministry of Health and the special structures undertake from the National School of Public Health, Management and Professional Development of Bucharest, the staff corresponding to the undertaken duties, while maintaining salary entitlements and status of each staff category.
(4) The Ministry of Health and its special structures undertake from the National School of Public Health, Management and Professional Development of Bucharest, the heritage corresponding to the duties undertaken in compliance with paragraph (1) according to the financial circumstances set up in accordance with Article 28 (1) of Law no. 82/1991, republished, as amended, through delivery-receipt protocol.

ARTICLE V
The discharge of payment liabilities registered according to the approved budget for implementation of national healthcare programs in 2013 and 2014, financed from the budget of the Ministry of Health, is ensured in 2014 from budget of the Ministry of Health, as follows:
a) from Title 20 "Goods and services", for activities implemented by the Ministry of Health and subordinated public institutions;
b) from Title 20 "Goods and services", for activities implemented based on contracts signed between special structures of the Ministry of Health and special facilities, others than subordinated to the Ministry of Health;
c) from Title 51 "Transfers between public administration facilities", for activities implemented by healthcare bed containing facilities subordinated to the Ministry of Health.
ARTICLE VI
Local public administration authorities may participate to finance administration and operation expenses, staff expenses, established in accordance with the law, goods and services, investments, major rehabilitations, reinforcement, extension and modernizing, supply with medical equipment of medical service providers, subordinated to other local public administration authorities, within budgetary credits approved for this purpose from own budgets.
ARTICLE VII
(1) The provisions of Article 45 (1) a) and c), Article 47, Article 48 (2) and (3), Article 49^1 (2), Article 52, Article 54 (1) and (4), Article 57, Article 242, Article 265 (2^1) and Article 362 b) of Law no. 95/2006 on healthcare reform, as amended, as amended through this Emergency Ordinance, come into force on 1 August 2014.
(2) The provisions of Article 220 and Article 262^1 of Law no. 95/2006, as amended, as amended through this Emergency Ordinance, come into force on 1 January 2015.
(3) The provisions of Article 20, Article 836 (1) m^1) and n) and Article 873 of Law no. 95/2006, as amended, as amended through this Emergency Ordinance, come into force within 10 days as of entry into force of this Emergency Ordinance.
(4) The Order on organisation and operation of NCP mentioned under Article 869 (1) is set up within 30 days as of the date of publication of this Emergency Ordinance.
(5) The Government Decision mentioned under Article 870 (2), as well as the Government Decision mentioned under Article 872 (3) and (4), Article 873 (1) d) and (5), Article 874 (3) b) and (4), Article 876 (1) a) (i) and (2), Article 877 (1) and Article 880 (2) and (4) are drafted within 30 days as of the date of publication of this Emergency Ordinance.
(6) The provisions concerning contraventional liability mentioned under Title XIX “Medical Devices” of Law no. 95/2006, as amended, come into force within 90 days as of entry into force of this Emergency Ordinance and are supplemented with those of Government Ordinance no. 2/2001 on the legal regime of contraventions, approved as amended through Law no. 180/2002, as amended.
(7) Title XIX “Medical Devices” comes into force within 90 days as of entry into force of this Emergency Ordinance.
ARTICLE VIII
(1) The assessment of providers of medical services, medicinal products, medical devices and medical and palliative care are performed by the Agency for Health Assessment and Quality, specialised structure subordinated to the Ministry of Health, set up within 90 days as of entry into force of this Emergency Ordinance, through Government Decision.
The assessment of medical service providers, medicinal products, medical devices and medical and palliative care at home
(2) According to the deadline mentioned under paragraph (1), the assessment criteria and methodology and the quantum of the tax for assessment are established through Order of the Minister of Health.

(3) Revenues obtained from the assessment activity lead to the set-up of own revenues of the specialised structure mentioned under (1).
(4) On entry into force of provisions mentioned under (1), Article 244 of Law no. 95/2006, as amended, is repealed.
ARTICLE IX
(1) Within 30 days as of entry into force of this Emergency Ordinance, Law no. 178/2000 on cosmetic products, republished in the Official Gazette of Romania, Part I, no. 120 of 17 February 2011, is repealed.
(2) The measures for set-up of the framework for enforcement of the provisions of Regulation (EC) no. 1.223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (amended) are approved through Government Decision, within 30 days as of entry into force of this Emergency Ordinance.
ARTICLE X
On entry into force of Title XIX "Medical Devices" of Law no. 176/2000 on medical devices, republished in the Official Gazette of Romania, Part I, no. 79 of 24 January 2005, as amended, is repealed.
ARTICLE XI
After (1) of Article 9 of Law no. 263/2004 on assurance of the continuity of primary medical assistance through performance centres, published in the Official Gazette of Romania, Part I, no. 568 of 28 June 2004, as amended, a new paragraph is introduced, (1^1), which reads as follows:
"(1^1) Financing of the ensurance of the consistency of services of primary medical assistance and the remuneration of the medical staff who performs its activity in remuneration of the medical staff performing its activity within medical permanence centres and the endowment of the emergency kit can also be performed by means of local budgets."
ARTICLE XII
Emergency Government Ordinance no. 71/2012 on assignment of the Ministry of Health as a central public procurement unit, published in the Official Gazette of Romania, Part I, no. 794 of 26 November 2006, approved as amended through Law no. 184/2013, is amended as follows:
1. Article 1 reads as follows:
"ARTICLE 1
The Ministry of Health, through its special structure performing special attributions in the field of medical devices, is assigned a central public procurement unit."
2. Under Article 2, paragraphs (1) and (2) read as follows:
"ARTICLE 2
(1) The centralised public acquisition unit mentioned under Article 1 signs framework agreements on behalf of and for public healthcare facilities from the network of the Ministry of Health and the network of local public administration authorities, as well as for public institutions subordinated to or coordinated by the Ministry of Health.
(2) Based on the framework agreements granted by the centralised public acquisition unit, public healthcare facilities and public institutions subordinated to or coordinated by the Ministry of Health sign and perform subsequent agreements, as approved by the Ministry of Health."
ARTICLE XIII
Article 1 of Emergency Government Ordinance no. 97/2010 on regulation of certain measures in the social health insurance system, published in the Official Gazette of Romania, Part I, no. 748 of 9 November 2010, as amended, is amended as follows:
"ARTICLE 1
The maximum number of jobs from the social health insurance system is 3,286, namely 296 for the National Health Insurance House, president included, and 2,990 for health insurance

houses, allocated, in accordance with the law, by the president of the National Health Insurance House, as approved by the Administration Council of the National Health Insurance House."

ARTICLE XIV

The Ministry of Public Finances is authorised to introduce, at the proposal of main credit ordinators, amendments issued from the enforcement of the provisions of this Emergency Ordinance within the structure of the state budget, the budget for activities wholly financed from own revenues and the budget of the Ministry of Health, as well as within the volume and structure of the FNUASS budget for 2014, while maintaining budgetary balance.

ARTICLE XV

Yearly, the level of transfers to the budget of the Single National Fund of Social Health Insurance mentioned under Article 54 (1) a) of Law no. 95/2006, as amended, should at least cover the level of amounts allocated the previous year for financing of national healthcare programs taken by the National Health Insurance House from the Ministry of Health in accordance with this Emergency Ordinance.

ARTICLE XVI

Law no. 95/2006 on healthcare reform, published in the Official Gazette of Romania, Part I, no. 372 of 28 April 2006, as amended and supplemented by this Emergency Ordinance, will be republished after approval of this Ordinance, and its texts will be renumbered.

PRIM-MINISTRU
VICTOR-VIOREL PONTA

Countersigned,
Minister of Health,
Gheorghe-Eugen Nicolăescu

Deputy Prime Minister, Minister of Regional Development and Public Administration,
Shhaideh Sevil,
Secretary of State

Deputy Prime Minister,
Interim Minister of Internal Affairs,
Gabriel Oprea

Deputy Prime Minister,
Minister for Public Finance,
Daniel Chiţoiu

Minister Delegate for Budget,
Liviu Voinea

Minister for National Education,
Remus Pricopie

Minister Delegate for Higher Education, Scientific Research and Technological Development,
Mihnea Cosmin Costoiu

Minister for National Defense,
Mircea Duşa

Minister for Transport,
Ramona-Nicole Mănescu

Minister for Foreign Affairs,
Titus Corlăţean

Minister for Labour, the Family, Social Protection and the Elderly,
Mariana Câmpeanu

Minister Delegate for Infrastructure Projects of National Interest and Foreign Investments,
Dan-Coman Şova

Bucharest, 29 January 2014.
No. 2.

MINISTRY OF HEALTH

ORDER no. 287 of 12 March 2014 on repeal of Order of the Minister of Health no. 912/2006 on approval of Regulations for authorisation of facilities able to perform clinical trials on medicinal products for human use

PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, no. 190 of 18 March 2014

On seeing the report for approval No. Cs. A.9.410/11.08.2011 of the Legal and Litigation Department no. NB 338/2014 and Notification no. 236 of 7 March 2014,

taking into account the provisions of Article 64 (4) and in line with Article 16 of Law 24/2000 on legislative technique norms for drawing up regulatory acts, republished, as amended,

based on Article 7 (4) of Government Decision No. 144/2010 on organisation and functioning of the Ministry of Health, as amended,

the minister of health hereby issues the following Order:

ARTICLE 1

Order of the Minister of Health no. 912/2006 on approval of Regulations for authorisation of facilities able to perform clinical trials on medicinal products for human use, published in the Official Gazette of Romania, Part I, no. 694 of 14 August 2006, is repealed.

ARTICLE 2

This Order is to be published in the Official Gazette of Romania, Part I.

Minister of health,
Nicolae Bănicioiu

Bucharest, 12 March 2014.
No. 287.

DECISION

No. 1/28.03.2014

on approval of amendment of Scientific Council Decision no. 2 of 22/02/2011 on posting on the NAMMD website of certain data concerning NAMMD authorised clinical trials

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 158/18.02.2013, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 28.03.2014, in accordance with Article 12(5) of Government Decision no. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Article I.: NAMMD Scientific Council Decision (SCD) no. 2 of 22.02.2011 is amended as follows:

1. Article 5 is amended as follows:

"**Article 5.** (1) Information from clinical trials for which applications for authorisation have been submitted as of 2014 is made publicly available.

(2) Information from clinical trials, published on the NAMMD website, is subject to monthly update."

2. Article 6 is amended as follows:

„Provisions of this Decision shall enter into force on 1 May 2014".

Article II.: The Annex to Scientific Council Decision no. 2 of 22.02.2011 is replaced with the Annex to this SCD.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

No.	Protocol code number	EudraCT Number	Investigational medicinal product tested	Comparator	Placebo	Therapeutic area	Applicant	Sponsor	International/ national	Name of the trial	Phase	Estimated number of patients for Romania	Number of patients enrolled in Romania	Date of NAMMD authorisation of the clinical trial	Date of Ethics Commission approval	Date of clinical trial start	End of the clinical trial	Temporary closure

DECISION

No. 3/28.03.2014

on approval of the Guideline on Good Pharmacovigilance Practices, Module XV – Safety communication

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 158/18.02.2013, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 28.03.2014, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following :

DECISION

Article 1. – The Guideline on Good Pharmacovigilance Practices, Module XV – Safety communication, is approved, in accordance with the Annexes which are integral parts of this Decision.

ARTICLE 2. – On this Decision coming into force, SCD no. 3/29.02.2008 on approval of the Guideline on Direct Healthcare Professional Communication is repealed.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines
and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

Guideline on Good Pharmacovigilance Practices (GVP)

Module XV – SAFETY COMMUNICATION

Date of entry into force: 24 January 2013

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ANNEX II to GVP-Module XV– Template for Direct Healthcare Professional Communication (DHPC)

XV.A. Introduction

This Module provides guidance to marketing authorisation holders, competent authorities in Member States and the European Medicines Agency (EMA) on how to communicate and coordinate safety information in the EU. Communicating safety information to patients and healthcare professionals is a public health responsibility and is essential for achieving the objectives of pharmacovigilance in terms of promoting the rational, safe and effective use of medicines, preventing harm from adverse reactions and contributing to the protection of patients' and public health (see Module I).

Safety communication is a broad term covering different types of information on medicines, including statutory information as contained in the product information (i.e. the summary of product characteristics (SmPC), package leaflet (PL) and the labelling of the packaging) and public assessment reports. Although some principles in this Module (i.e. Section XV.B.1 and B.2.) apply to all types of safety communication, the module itself focuses on the communication of 'new or emerging safety information', which means new information about a previously known or unknown risk of a medicine which has or may have an impact on a medicine's benefit-risk balance and its condition of use. Unless otherwise stated, the term 'safety communication' in this module should be read as referring to emerging safety information.

Experience so far has demonstrated the need to coordinate safety communication within the EU regulatory network.

The occurrence of new concerns is generally accompanied by a serious increase in public interest; it is thus important that clear and consistent messages are provided across the EU in a timely manner. The new legislation on pharmacovigilance therefore includes a number of provisions to strengthen safety communication and its coordination[1].

Communication of important new safety information on medicinal products should take into account the views and expectations of concerned parties, including patients and healthcare professionals, with due consideration given to relevant legislation. This Module addresses some aspects of the interaction with concerned parties and supplements the specific guidance given in Module XI on public participation as well as the guidance on communication planning given in Module XII.

[1] Directive 2010/84/EU amending Directive 2001/83/EC (the latter is referenced as DIR), Regulation (EU) No 1235/2010 amending Regulation (EC) No 726/2004 and in the Commission Implementing Regulation (EU) No 520/2012 on the Performance of Pharmacovigilance Activities Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC.

Communication is distinct from transparency, which aims to provide public access to information related to data assessment, decision-making and safety monitoring performed by competent authorities. The new EU legislation on pharmacovigilance envisages an unprecedented level of transparency. Transparency provisions applicable to each pharmacovigilance process are provided in the relevant GVP Modules.

Section XV.B. of this Module describes principles and means of safety communication. Section XV.C. provides guidance on the coordination and dissemination of safety communications within the EU network. Both sections give particular consideration to direct healthcare professional communications (DHPCs), and provide specific guidance for preparing them. This is because of the central importance of DHPCs in targeting healthcare professionals and because of the level of coordination required between marketing authorisation holders and competent authorities in their preparation.

XV.B. Structures and processes

XV.B.1. Objectives of safety communication

Safety communication aims at:

- providing timely, evidence-based information on the safe and effective use of medicines;
- facilitating changes to healthcare practices (including self-medication practices) where necessary;
- changing attitudes, decisions and behaviours in relation to the use of medicines;
- supporting risk minimisation behaviour;
- facilitating informed decisions on the rational use of medicines.

In addition to the above effective, high quality safety communication can support public confidence in the regulatory system.

XV.B.2. *Principles of safety communication*

The following principles of safety communication should be applied:

- The need for communicating safety information should be considered throughout the pharmacovigilance and risk management process, and should be part of risk assessment (see Module XII).
- There should be adequate coordination and cooperation between the different parties involved in issuing safety communications (e.g. competent authorities, other public bodies and marketing authorisation holders).

• Safety communication should deliver relevant, clear, accurate and consistent messages and reach the right audiences at the right time for them to take appropriate action.

•Safety communication should be tailored to the appropriate audiences (e.g. patients and healthcare professionals) by using appropriate language and taking account of the different levels of knowledge and information needs whilst maintaining the accuracy and consistency of the information conveyed.

• Information on risks should be presented in the context of the benefits of the medicine and include available and relevant information on the seriousness, severity, frequency, risk factors, time to onset, reversibility of potential adverse reactions and, if available, expected time to recovery.

- Safety communication should address the uncertainties related to a safety concern. This is of particular relevance for emerging information which is often communicated while competent authorities are conducting their evaluations; the usefulness of communication at this stage needs to be balanced against the potential for confusion if uncertainties are not properly represented.
- Information on competing risks such as the risk of non-treatment should be included where appropriate.
- The most appropriate quantitative measures should be used when describing and comparing risks, e.g. the use of absolute risks and not just relative risks; for risk comparisons, denominators should be the same in size. The use of other tools such as graphical presentation of the risk and/or the benefit-risk balance may also be used.
- Patients and healthcare professionals should, where possible, be consulted and messages pre-tested early in the preparation of safety communication, particularly on complex safety concerns (see Module XII).
- Where relevant safety communication should be complemented at a later stage with follow-up communication e.g. on the resolution of a safety concern or updated recommendations.
- The effectiveness of safety communication should be evaluated where appropriate and possible (see XV.B.7.).
- Safety communications should comply with relevant requirements relating to individual data protection and confidentiality.

XV.B.3. Target audiences

The primary target audiences for safety communication issued by regulatory authorities and marketing authorisation holders should be patients and healthcare professionals who use (i.e. prescribe, handle, dispense, administer or take) medicinal products.

As primary target audiences, healthcare professionals play an essential role. Effective safety communication enables them to give clear and useful information to their patients, thereby promoting patient safety and confidence in the regulatory system. Both healthcare professionals in clinical practice and those involved in clinical trials should be provided with appropriate information on any safety concern at the same time.
Patient, consumer and healthcare professional organisations can play a role as multipliers as they can disseminate important safety information to target audiences.
The media is also a target audience for safety communication. The capacity of the media to reach out to patients, healthcare professionals and the general public is a critical element for amplifying new and important information on medicines. The way safety information is communicated through the media will influence the public perception and it is therefore important that the media receives safety information directly from the competent authorities in addition to the information they receive from other sources, such as from the marketing authorisation holders.

XV.B.4. Content of safety communication

Taking into account the principles in XV.B.2., safety communication should contain:

- important emerging information on any authorised medicinal product which has an impact on the medicine's benefit-risk balance under any conditions of use;
- the reason for initiating safety communication clearly explained to the target audience;
- any recommendations to healthcare professionals and patients on how to deal with a safety concern;
- when applicable, a statement on the agreement between the marketing authorisation holder and the competent authority on the safety information provided;
- information on any proposed change to the product information (e.g. the summary of product characteristics (SmPC) or package leaflet (PL));
- a list of literature references, when relevant or a reference to where more detailed information can be found;
- where relevant, a reminder of the need to report suspected adverse reactions in accordance with national spontaneous reporting systems.

The information in the safety communication shall not be misleading and shall be presented objectively [Law 95/2006[2], Article 818 (1)]. Safety information should not include any material or statement which might constitute advertising within

[2] Law 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended, hereinafter 'Law 95/2006'

the scope of Law 95/2006 on healthcare reform – Title XVII – The medicinal product, as amended.

XV.B.5. Means of safety communication

Communication tools and channels[3] have become more numerous and varied over time, offering the public more information than was previously possible. The use of this increasing variety of means should be considered when issuing safety communication in order to reach the target audiences and meet their growing expectations. Different communication tools and channels are discussed below in sections XV.B.5.1.-XV-B.5.9.

XV.B.5.1. Direct Healthcare Professional Communication (DHPC)

A direct healthcare professional communication (DHPC) is defined in this document as a communication intervention by which important safety information is delivered directly to individual healthcare professionals by a marketing authorisation holder or a competent authority, to inform them of the need to take certain actions or adapt their practices in relation to a medicinal product. DHPCs are not replies to enquiries from healthcare professionals, nor are they meant as educational material for routine risk minimisation activities.

The preparation of DHPCs involves cooperation between the marketing authorisation holder and the competent authority. Agreement between these two parties should be reached before a DHPC is issued by the marketing authorisation holder. The agreement will cover both the content of the information (see XV.B.4.) and the communication plan, including the intended recipients and the timetable for disseminating the DHPC (see Module XII).

Where there are several marketing authorisation holders of the same active substance for which a DHPC is to be issued, a single consistent message should normally be delivered.

Whenever possible, it is advised that healthcare professionals' organisations or learned societies are involved as appropriate during the preparation of DHPCs to ensure that the information they deliver is useful and adapted to the target audience.

A DHPC may be complemented by other communication tools and channels and the principle of providing consistent information should apply (XV.B.2.).

A DHPC may be an additional risk minimisation measure as part of a risk management plan (see Modules V and XV).

A DHPC should be disseminated in the following situations when there is a need to take immediate action or change current practice in relation to a medicinal product:

• suspension, withdrawal or revocation of a marketing authorisation for safety reasons;

[3] In line with this Chapter, the tools and channels are equally described, since they frequently mix and there are no uniform opinions on their classification.

• an important change to the use of a medicine due to the restriction of an indication, a new contraindication, or a change in the recommended dose due to safety reasons;
• a restriction in availability or discontinuation of a medicine with potential detrimental effects on patient care.

Other situations where dissemination of a DHPC should be considered are:
• new major warnings or precautions for use in the product information;
• new data identifying a previously unknown risk or a change in the frequency or severity of a known risk;
• substantiated knowledge that the medicinal product is not as effective as previously considered;
• new recommendations for preventing or treating adverse reactions or to avoid misuse or medication error with the medicinal product;
• ongoing assessment of an important potential risk, for which data available at a particular point in time are insufficient to take regulatory action (in this case, the DHPC should encourage close monitoring of the safety concern in clinical practice and encourage reporting, and possibly provide information on how to minimise the potential risk).
A competent authority may disseminate or request the marketing authorisation holder to disseminate a DHPC in any situation where the competent authority considers it necessary for the continued safe and effective use of a medicinal product.

XV.B.5.2. Documents in lay language

Communication material in lay language (e.g. using a questions & answers format) helps patients and the general public to understand the scientific evidence and regulatory actions relating to a safety concern. Lay language documents should contain the competent authority's recommendations and advice for risk minimisation for patients and healthcare professionals in relation to the safety concern, and should be accompanied by relevant background information.
Lay language documents are generally useful to members of the public who have an interest in the subject but do not have a scientific or regulatory background. Reference should be made to other communication materials on the topic to direct readers to where they can find further information.
Competent authorities publish lay language documents on their national medicines web-portals and may additionally disseminate them to relevant parties such as patients and healthcare professionals' organisations.
Whenever possible, it is advised that patients and healthcare professionals are involved during the preparation of lay language documents to ensure that the information they deliver is useful and adapted to the target audience.

XV.B.5.3. Press communication

Press communication includes press releases and press briefings which are

primarily intended for journalists.
Competent authorities may send press releases directly to journalists in addition to publishing them on their websites. This ensures that journalists, in addition to obtaining information from other sources, receive information that is consistent with the authority's scientific assessment. Interaction with the media is an important way to reach out to a wider audience as well as to build trust in the regulatory system.
Press releases may also be prepared and published by marketing authorisation holders. Their press releases may reflect the position of the marketing authorisation holder on a safety topic but should also make reference to any regulatory action taken by the competent authority. Relevant ongoing reviews should be mentioned in any communication by the marketing authorisation holder.
Although aimed at journalists, press releases will be read by other audiences such as healthcare professionals, patients and the general public. Reference should therefore be made to related communication materials on the topic. In cases where a DHPC is also prepared, healthcare professionals should ideally receive it prior to or around the same time of the publication or distribution of a press release so that they are better prepared to respond to patients.
Press briefings with journalists should be considered by competent authorities for safety concerns or other matters relating to the safety of medicinal products that are of high media interest or when complex or public-health-sensitive messages need to be conveyed.

XV.B.5.4. Website

A website is a key tool for members of the public (including patients and healthcare professionals) actively searching the internet for specific information on medicinal products. Competent authorities as well as marketing authorisation holders should ensure that important safety information published on websites under their control is easily accessible and understandable by the public. Information on websites should be kept up-to-date, with any information that is out-of-date marked as such or removed.
The new legislation on pharmacovigilance foresees the creation of an EU medicines web portal which will contain information on all medicines authorised in the EU [Article 26 of Regulation (EU) No 1235/2010]. This web portal will become a key tool for communicating up-to-date safety information to EU citizens and will contain information in all EU official languages. Each Member State shall set up and maintain a national medicines web-portal which shall be linked to the EU medicines web-portal [Law 95/2006, Article 818]. Until the web portal is fully established and into operation, the Agency's website will be acting as an interim platform to convey this important up-to-date safety information.

XV.B.5.5. Other web-based communications

Online safety information may also be disseminated via other web tools. When

using newer, more rapid communication channels, special attention should be paid to ensure that the accuracy of the information released is not compromised. Communication practices should take into account emerging communication tools used by the various target audiences.

XV.B.5.6. Bulletins and newsletters

Bulletins and newsletters provide at regular intervals new information about medicines and their safety and effectiveness. Competent authorities can reach a large audience with these tools by using web-based and other available means.

XV.B.5.7. Inter-authority communication

When one competent authority takes regulatory action on a particular safety concern, other competent authorities usually need to respond to enquiries or communicate on the same issue. The use of inter-authority communication material, such as lines-to-take should be considered. Lines-to-take are documents specifically prepared by a competent authority to assist its own staff and those of co-operating authorities in responding to external enquires or communicating on a specific safety issue.

XV.B.5.8. Responding to enquiries from the public

Competent authorities and marketing authorisation holders should have systems in place for responding to enquiries about medicines from individual members of the public. Responses should take into account the information which is in the public domain and should include the relevant recommendations to patients and healthcare professionals issued by competent authorities. Where questions relate to individual treatment advice, the patient should be advised to contact a healthcare professional.

In this respect, Articles 797(2) and 809(1) of Law 95/2006, as amended, apply to marketing authorisation holders.

XV.B.5.9. Other means of communication

In addition to those discussed above, there are other tools and channels such as publications in scientific journals and journals of professional bodies.

Some tools and channels may be used in the context of risk management; risk minimisation measures often include specific programmes for risk communication. Tools used in such programmes, such as patient alert cards or healthcare professional safety guidance, are outside the scope of this module and are described in more detail in Module XVI.

XV.B.6. Effectiveness of safety communication

Safety communication is considered effective when the message transmitted is received and understood by the target audience in the way it was intended, and appropriate action is taken by the target audience. Adequate mechanisms should be introduced in order to measure the effectiveness of the communication based

on clear objectives. Measuring effectiveness allows lessons to be learned and helps in making decisions on prioritising and adapting tools and practices to meet the needs of the target audiences. A research-based approach will normally be appropriate in order to establish that safety communications have met the standard of XV.B.2. This approach may measure different outcomes, including behaviour, attitudes, and knowledge. When evaluating the effectiveness of safety communication, the scope of the evaluation may be broadened to include factors other than the performance of the individual tools used in the safety communication (see Module XVI).
In the case of DHPCs, the marketing authorisation holder should be responsible for evaluating the dissemination of the DHPCs they prepare and should inform the competent authorities of the outcome and of any difficulties identified (e.g. problems related to the list of recipients or the timing and mechanism of dissemination). Appropriate action should be taken as needed to correct the situation or prevent similar problems in the future.

XV.B.7. Quality system requirements for safety communication

In accordance with the quality system requirements in Module I, procedures should be in place to ensure that safety communications comply with the principles in XV.B.2. as appropriate.
In particular, the communications should be subject to quality controls to ensure their accuracy and clarity. For this purpose review procedures with allocated responsibilities should be followed and documented.

XV.C. Operation of the EU regulatory network

XV.C.1. Coordination of safety announcements in the EU

In the EU, patients and healthcare professionals increasingly look at competent authorities as providers of important information on medicines. For safety communication to be effective, adequate coordination and cooperation is required within the EU regulatory network[4]. A good level of coordination of safety communication is of particular importance so that healthcare professionals and patients receive consistent information on regulatory decisions in the EU.
When issuing safety announcements, competent authorities may make use of the different tools and channels described in XV.B.5. Prior to the publication of a safety announcement, the Member States, the Agency or the European Commission shall inform each other not less than 24 hours in advance, unless urgent public announcements are required for the protection of public health [Law 95/2006, as amended, Article 818[1](2)].
For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be responsible for the coordination between

[4] Competent authorities of Member States, EMA and the European Commission.

national competent authorities of safety amendments [Law 95/2006, as amended, Article 818¹(3)].
For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be responsible for the coordination between national competent authorities of safety announcements [Law 95/2006, as amended, Article 818¹].
For practical reasons, considering the potential for overlap between transparency measures and active communications and in order to focus on those topics of major health relevance, not all safety information made public by a Member State or the Agency will be subject to systematic exchange and coordination. Only safety announcements that relate to the following and that pertain to active substances contained in medicinal products authorised in more than one Member State require coordination within the EU regulatory network:

- the suspension, withdrawal or revocation of a marketing authorisation due to changes to its benefit-risk balance;
- the start or finalisation of an EU referral procedure for safety reasons;
- restriction of indication or treatment population or the addition of a new contraindication;
- dissemination of a DHPC agreed by relevant competent authorities of a Member State or the Agency (see XV.C.2.1.);
- other emerging safety concerns judged by a national competent authority or the Agency to be likely to give rise to public or media interest in more than one Member State (e.g. a publication of important safety findings in a (scientific) journal, safety-related regulatory action taken in a Member State or in a country outside the EU).

XV.C.1.1. Process for exchange and coordination of safety announcements
A competent authority of a Member State or the Agency shall inform the EU regulatory network prior to the publication of a safety announcement that pertains to active substances contained in medicinal products authorised in more than one Member State and that refer to any of the situations identified in XV.C.1. It shall include a timetable for the information being made public [Law 95/2006, Article 818¹(3)]. Whenever possible the safety announcement shall be sent to the network under embargo no less than 24 hours in advance of publication [Law 95/2006, Article 818¹(2)], in order to allow the members of the EU regulatory network to prepare or plan their own communication if necessary. Under the coordination of the Agency, the Member States shall make all reasonable efforts to agree on a common message [Law 95/2006, Article 818¹(3)].
The Agency should decide for each case, on the basis of the public health relevance and urgency of the safety concern, the population and number of Members States affected and the potential for media attention, whether further action in addition to the dissemination of the safety announcement is needed,

such as:

- the preparation of lines-to-take (see XV.B.5.7.) which should be disseminated to the EU regulatory network. The lines-to-take document should help the EU regulatory network to respond to any request for information which may follow the publication of the safety announcement;
- the preparation of an Agency safety announcement in addition to that of the Member State, which should also be disseminated under embargo to the EU regulatory network together with a timetable for its publication.

The Agency should prepare lines-to-take documents and any Agency safety announcement together with the Member State(s) who originated the process and the Pharmacovigilance Risk Assessment Committee (PRAC) Lead Member State or the PRAC Rapporteur, as appropriate. The PRAC, as well as the Committee for Medicinal Products for Human Use (CHMP) or the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh), should also be consulted as necessary.

Coordination of safety announcements should be done in cooperation with the concerned marketing authorisation holder(s). Whenever possible, the Agency and the competent authorities in Member States should provide any safety announcement prior to its publication to the concerned marketing authorisation holder(s), together with the timetable for the information being made public. Any information of a personal or commercially confidential nature shall be deleted unless its public disclosure is necessary for the protection of public health [Law 95/2006, Article 818^{1}(4)].

The exchange and coordination of safety announcements within the EU regulatory network should make use of the EU Early Notification System (ENS). The ENS was developed for use by the Agency to provide advance notice to competent authorities in Member States and the European Commission of safety information on centrally authorised products. This system should also be used by competent authorities in Member States for the purpose of exchanging and coordinating safety announcements.

The ENS includes the Heads of Medicines Agencies (HMA), the members of the PRAC, CHMP, CMDh, the operational contact points for safety announcements at the competent authority in Member States, the European Commission and the Agency. Operational contact points should ensure that any information exchanged via the system reaches in a timely manner the relevant staff within each competent authority, including relevant staff working within the communications departments.

Safety announcements from the EU regulatory network should be shared with international partners in accordance with the guidance provided in Module XIV, subject to embargo and any specific confidentiality arrangements in place.

As a complement to the coordination of safety announcements within the EU regulatory network, competent authorities in Member States and the Agency should interact with concerned stakeholders in the EU (mainly patients' and

healthcare professionals' organisations), who can play a key role in reviewing and disseminating information to the end users (patients and healthcare professionals). It is recommended that national competent authorities and the Agency keep up-to-date contact details of relevant patients, and healthcare professionals' organisations.

XV.C.1.2. Exchange of safety information performed by third parties

There are situations where emerging safety information is to be published or has been published by a party other than a competent authority of a Member State or the Agency (e.g. scientific journals, learned societies). Competent authorities should bring to the attention of the EU regulatory network any such safety information that they become aware of, together with the timing of the publication if known. Where necessary and after evaluation of the information, the Agency should prepare and disseminate a lines-to-take document or an Agency safety announcement to address the information from the third party (see XV.C.1.1.).

In the context of collaboration with authorities outside the EU, the Agency or a competent authority of a Member State may become aware of safety announcements to be published by these authorities (see Module XIV). In these cases the Agency should, as necessary, prepare and disseminate lines-to-take or safety announcements within the EU regulatory network. In all cases, the terms of any relevant confidentiality agreements with non-EU regulatory authorities and the embargoes on the information received should be respected.

XV.C.1.3. Requirements for the marketing authorisation holder in the EU

As soon as a marketing authorisation holder in the EU intends to make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal product, and in any event at the same time or before the public announcement is made, the marketing authorisation holder shall be required to inform the competent authorities in Member States, the Agency and the European Commission [Law 95/2006 Article 818[1]]. This should apply to announcements intended for the EU as well as outside the EU (when they concern products authorised in the EU or those for which an opinion under Article 58 of Regulation (EC) 726/2004 has been given).

Informing the authorities at the same time as the public (i.e. without advance notice to the authorities) should only occur exceptionally and under justified grounds. Whenever possible, the information should be provided under embargo at least 24 hours prior to its publication. The marketing authorisation holder shall ensure that information to the public is presented objectively and is not misleading [Law 95/2006, Article 818[1](1)].

Whenever a marketing authorisation holder becomes aware that a third party (see XV.C.1.2.) intends to issue communication that could potentially impact the benefit-risk balance of a medicinal product authorised in the EU, the marketing authorisation holder should inform the relevant competent authorities in Member

States and the Agency and make every effort to share the content of the communications with the relevant authorities.

XV.C.1.4. Consideration for third parties

Third parties (e.g. scientific journals, learned societies, patients' organisations) are encouraged to inform the Agency and the competent authorities in Member States of any relevant emerging information on the safety of medicines authorised in the EU and, if publication is planned, to share the information ahead of publication.

XV.C.1.5. Languages and translations

Consistent messages should reach the public across the EU in a timely manner and in the official languages of the Member States as specified by the Member States where the medicinal product is placed on the market.

For the purpose of coordination, the Agency shall use English to inform the EU regulatory network of any safety announcement. When informing the Agency, the competent authorities in Member States are encouraged to provide English translations of their safety announcements for the purpose of initiating the coordination process. In the absence of a full text translation, an English summary should be provided.

XV.C.2. Direct Healthcare Professional Communications in the EU

In the EU, a direct healthcare professional communication (DHPC) (see XV.B.5.1.) is usually disseminated by one or a group of marketing authorisation holders for the respective medicinal product(s) or active substance(s), either at the request of a national competent authority or the Agency, or on the marketing authorisation holder's own initiative. The marketing authorisation holder should seek the agreement of the relevant national competent authorities or the Agency regarding the content of a DHPC (and communication plan) prior to dissemination.

XV.C.2.1. Processing of DHPCs

The situations when a DHPC is necessary or should be considered are provided in XV.B.5.1. When drafting a DHPC, the template (see Annex II) and the guidance provided in the annotations in the template should be followed as appropriate.

The roles and responsibilities of the competent authorities in a Member State, the Agency and marketing authorisation holders in the preparation and processing of DHPCs depend on the route of authorisation of the medicinal products concerned:

- for centrally authorised products and for products subject to an EU referral procedure for safety reasons, the relevant marketing authorisation holders should submit the draft DHPC and communication plan (including the intended recipients and the timetable for disseminating the DHPC) to the Agency, which

should coordinate the review process by its scientific committees (i.e. PRAC and CHMP) and CMDh.
• for products authorised through the mutual recognition or decentralised procedure, the marketing authorisation holder should submit the draft DHPC and communication plan to the Reference Member State, which should co-ordinate the process with the marketing authorisation holder, while keeping the Concerned Member States informed of any proposed action.
• for nationally authorised products not authorised through the mutual recognition or decentralised procedure, the marketing authorisation holder should submit the draft DHPC and any communication plan to the competent authorities of the Member States where the products are authorised.

The marketing authorisation holder should allow a minimum of two working days for comments. However, whenever possible more time should be allowed. The timing may be adapted according to the urgency of the situation.
The Agency will coordinate the review of DHPCs within its scientific committees/groups as appropriate (i.e. involvement of PRAC, and finalisation by CHMP or CMDh) The PRAC should always be involved in the review of DHPCs related to a safety concern being discussed at the PRAC and the DHPC should form part of the PRAC assessment (see Module XII). The Agency may also request advice from the PRAC on issues related to other safety communications.
Once the content of a DHPC and communication plan from the MAH are agreed by national competent authorities or the Agency, the national competent authorities or the Agency should exchange the final DHPC and communication plan using the early notification system (see XV.C.1.1.), and the Agency should coordinate any subsequent safety announcement as appropriate using the process described in XV.C.1.1. The early notification system is only used if the DHPC concerns an active substance authorised in more than one Member State.
In cases where an authority outside the EU requests the dissemination of a DHPC in their territory for a product also authorised in the EU, the marketing authorisation holder should notify the relevant competent authorities in the EU. This is part of the legal requirement under which the marketing authorisation holder shall notify the competent authorities of any new information which may impact the benefit-risk balance of a medicinal product [Regulation 1235/2010, Article 16(2) and Law 95/2006, Article 728(2)]. The need for any subsequent communication, e.g. a DHPC, in the EU should be considered and agreed on a case-by-case basis.
A flow chart describing the processing of DHPCs is provided in Annex I - Figure XV.I at the end of this Module.

XV.C.2.2. Translation of DHPCs

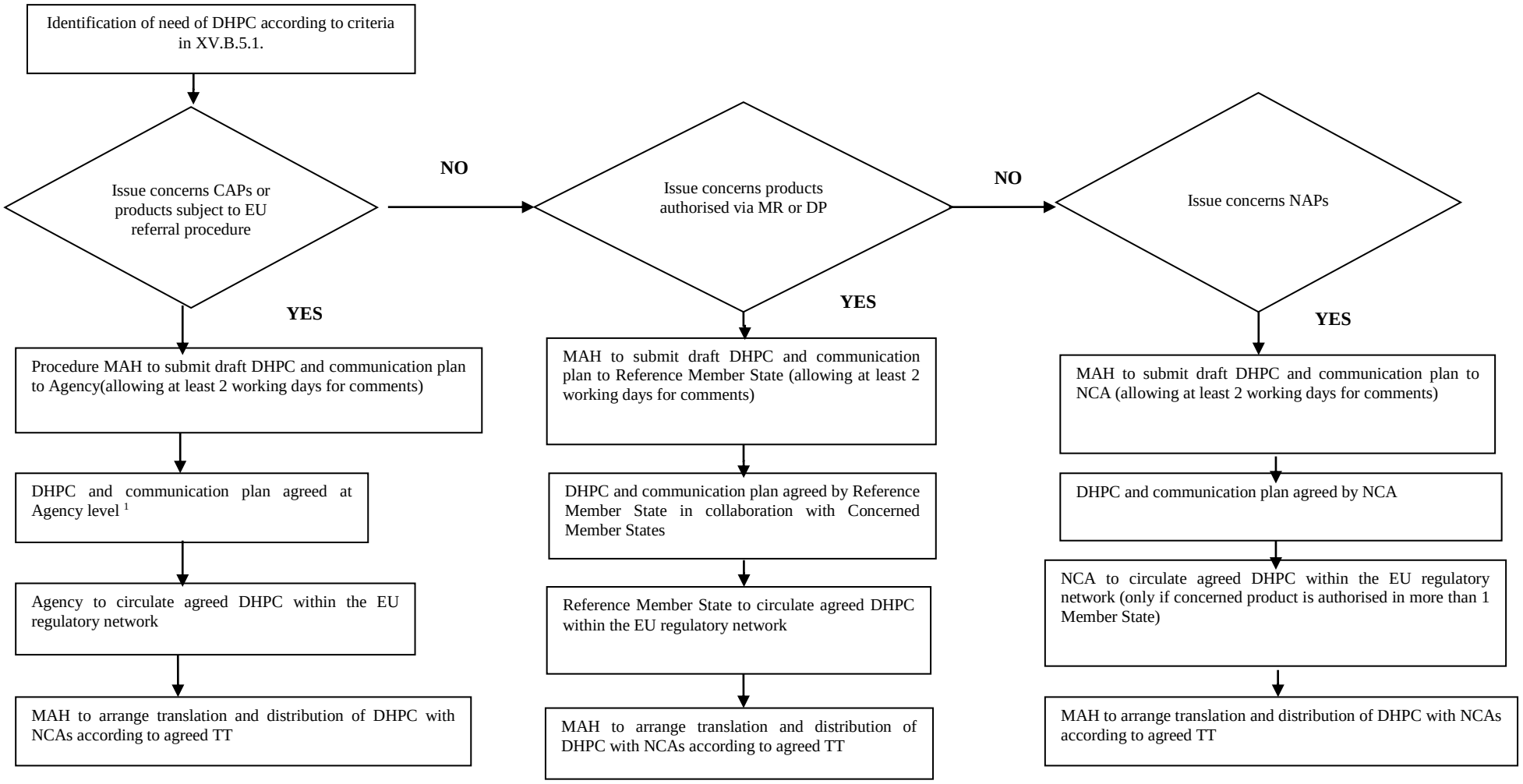
For centrally authorised products, products subject to an EU referral procedure for safety reasons and, in most cases, for products authorised through the mutual recognition or decentralised procedure, the working language for preparing the

DHPCs will normally be English.
Once the text of the DHPC is agreed, the marketing authorisation holder should prepare translations in the official languages of the Member States, as specified by the Member States where the DHPC is to be distributed. The draft translations should be submitted to the Member States for a language review within a reasonable timeframe (no more than two working days).
For centrally authorised products and products subject to an EU referral procedure for safety reasons, the relevant marketing authorisation holder should provide the Agency with a complete set of all final EU official language versions as well as any additional related communication documents.

XV.C.2.3. Publication of DHPCs

The competent authorities may publish the final DHPC. The timing for such publication should be aligned to that of the dissemination of DHPC in the Member States. The competent authorities may also issue an additional safety announcement, and disseminate the DHPC to relevant healthcare professionals' organisations as appropriate.

Figure VX.1: Flow chart for the processing of Direct Healthcare Professional Communications (DHPCs) in the EU



[1] The Agency will coordinate the review of DHPC within its scientific committees (i.e. PRAC and CHMP) and CMDh.

TEMPLATE FOR DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC)

<Date>

<Active substance, name of the medicinal product and main message *(e.g. entry of a warning or contraindication)>*

Dear Healthcare Professional,

<Marketing Authorisation Holder> wishes to inform you about:

Summary*

- <A brief description of the safety concern, recommendations for risk minimisation (*e.g. contraindications, warnings, precautions*) and, if applicable, switch to alternative treatment>

- <Recall information, if applicable, level (pharmacy or patient level) and date of recall>

< A statement indicating that the information has been endorsed by a national Competent Authority/the Agency, if applicable >

Safety information on safety concern and recommendation

<Important details about the safety concern (adverse reaction, seriousness, statement on the suspected causal relationship, e.g. the pharmacodynamic mechanism, if known, temporal relationship, positive re-challenge or de-challenge, risk factors), also indicating the reason for disseminating the DHPC at this point in time.>

<An estimation of the frequency of the adverse reaction or reporting rates with estimated patient exposure>

<A statement indicating any association between the adverse reaction and off-label use, if applicable>

<If needed, details on the recommendations for risk minimisation >

<Placing of the risk in the context of the benefit>

<A statement about newly submitted DHPCs, referring to the current safety issue>
<A schedule for follow-up action(s) by the Marketing Authorisation Holder/Competent Authority, if applicable>

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* ***Style guide: The Summary section should be in larger font size than the other sections of the DHPC and should preferably use markers.***

Further information

<Link/Reference to other available relevant information, e.g. information posted on the website of the competent authority>

<Therapeutic indications for the respective medicinal product, if not previously mentioned>

Call for reporting

<A reminder of the need to report adverse reactions in accordance with the national spontaneous reporting system>

"It is important to report any suspected adverse reaction associated with the administration of …… to the National Agency for Medicines and Medical Devices, in accordance with the national system for spontaneous reporting, using the "Adverse reaction reporting form".

<Please specify whether the medicinal product is subject to additional monitoring as well as the grounds for this decision>

<Details (name, postal address, fax number, website address) on how to access the national spontaneous reporting system>

The "Adverse reaction reporting form" is available on the website of the National Agency for Medicines and Medical Devices (www.anm.ro), under section Medicinal products for human use/Report an adverse reaction. This may be submitted to the National Agency for Medicines and Medical Devices by post, fax or e-mail:

The National Agency for Medicines and Medical Devices
The National Pharmacovigilance Centre
48 Av. Sanatescu St.,
Sector 1, Bucharest, 011478 - RO
Romania
Telephone number: + 4 0757 117 259
Fax number: +40 213 163 497
E-mail address: adr@anm.ro
You can also report suspected adverse reactions to ..... – contact coordinates:

……."

Contact coordinates of the local representative of the Marketing Authorisation Holder

<Contact point details for access to further information, including relevant website address(es), telephone number(s) and a postal address>

Annexes

<Text of the revised Product Information (with changes made visible)>

<Detailed scientific information, if necessary>

<List of literature references, if applicable>

DECISION

No. 4/28.03.2014

on approval of abbreviated Romanian Standard Terms for labelling of oral, oromucosal, dental, cutaneous and transdermal, vaginal, rectal, inhalation and tracheopulmonary preparations, in line with European Pharmacopoeia approved terms

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 158/18.02.2013, in accordance with the Regulation on organisation and operation of the NAMMD Scientific Council, Article 8 (1), adopts through written procedure the following

DECISION

Sole article - The abbreviated Romanian Standard Terms for labelling of oral, oromucosal, dental, cutaneous and transdermal, vaginal, rectal, inhalation and tracheopulmonary preparations, in line with European Pharmacopoeia approved terms are approved, in accordance with the Annex which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX
to SCD no. 4/28.03.2014

ABBREVIATED ROMANIAN STANDARD TERMS

for

PHARMACEUTICAL FORMS

in accordance with the

Short European Standard Terms

(***Short Terms / Patient friendly)***

approved by the

European Pharmacopoeia Commission,
European Directorate for the Quality of Medicines (EDQM),
European Council, Strasbourg

The following **Abbreviated Romanian Standard Terms** can only be used for labelling of the listed pharmaceutical forms, if the size of the label does not allow imprinting of the full Standard term.

Preparate orale – forme lichide şi semisolide *Oral preparations – liquid and semi-solid forms*			
Termen complet		**Termen prescurtat**	
română	**engleză**	**română**	**Engleză**
Oral drops, solution	*Oral drops, solution*	Picături orale*	*oral drops**
Picături orale, suspensie	*Oral drops, suspension*	Picături orale*	*oral drops**
Picături orale, emulsie	*Oral drops, emulsion*	Picături orale*	*oral drops**
Oral solution	*Oral solution*	Lichid oral*	*oral liquid**
Suspensie orală	*Oral suspension*	Lichid oral*	*oral liquid**
Emulsie orală	*Oral emulsion*	Lichid oral*	*oral liquid**

Preparate orale – forme solide *Oral preparations – solid forms*			
Termen complet		**Termeni prescurtat**	
română	**engleză**	**română**	**Engleză**
Capsulă	Capsule, hard	Capsulă*	*Capsule**
Capsulă moale	Capsule, soft	Capsulă*	*Capsule**
Capsulă gastrorezistentă	Gastro – resistant capsule, hard	Capsulă gastrore-zistentă*	*Gastro-resistant capsule**
Capsulă moale gastrorezistentă	Gastro-resistant capsule, soft	Capsulă gastrore-zistentă*	*Gastro-resistant capsule**
Capsulă cu eliberare prelungită	Prolonged - release capsule, hard	Capsulă cu eliberare prelungită*	*Prolonged-release capsule**
Capsulă moale cu eliberare prelungită	Prolonged - release capsule, soft	Capsulă cu eliberare prelungită*	*Prolonged-release capsule**
Drajeu	Coated tablet	Drajeu*	*Tablet**
Comprimat filmat	Film - coated tablet	Comprimat*	*Tablet**

Preparate bucofaringiene *Oromucosal preparations*			
Termen complet		**Termen prescurtat**	
română	**engleză**	**română**	**Engleză**
Soluţie bucofaringiană	*Oromucosal solution*	Lichid bucofaringian*	Oromucosal liquid*
Suspensie bucofaringiană	*Oromucosal suspension*	Lichid bucofaringian*	Oromucosal liquid*
Spray bucofaringian, soluţie	*Oromucosal spray, solution*	Spray bucofaringian*	Oromucosal spray*
Spray bucofaringian, suspensie	*Oromucosal spray, suspension*	Spray bucofaringian*	Oromucosal *spray**
Spray bucofaringian, emulsie	*Oromucosal spray, emulsion*	Spray bucofaringian*	Oromucosal *spray**

Spray sublingual, solutie	*Sublingual spray, solution*	Spray sublingual*	*Sublingual spray**
Spray sublingual, suspensie	*Sublingual spray, suapension*	Spray sublingual*	*Sublingual spray**
Spray sublingual, emulsie	*Sublingual spray, emulsion*	Spray sublingual*	*Sublingual spray**
Comprimat de supt	*Compressed lozenge*	Pastilă*	Lozenge*

Preparate dentare *Preparations for dental use*			
Termen complet		**Termen prescurtat**	
română	**engleză**	**română**	**Engleză**
Soluţie dentară	*Dental solution*	Lichid dentar*	*Dental liquid**
Suspensie dentară	*Dental suspension*	Lichid dentar*	*Dental liquid**
Emulsie dentară	*Dental emulsion*	Lichid dentar*	*Dental liquid**

Preparate cutanate şi transdermice *Cutaneous and transdermal preparations*			
Termen complet		**Termen prescurtat**	
română	**engleză**	**română**	**Engleză**
Spray cutanat, soluţie	*Cutaneous spray, solution*	Spray cutanat*	*Cutaneous spray**
Spray cutanat, suspensie	*Cutaneous spray, suspension*	Spray cutanat*	*Cutaneous spray**
Spray cutanat, emulsie	*Cutaneous spray, emulsion*	Spray cutanat*	*Cutaneous spray**
Spray cutanat, Ointment	Cutaneous spray, ointment	Spray cutanat*	*Cutaneous spray**
Spray cutanat, pulbere	*Cutaneous spray, powder*	Spray cutanat*	*Cutaneous spray**

Cutaneous solution	*Cutaneous solution*	Lichid cutanat*	*Cutaneous liquid**
Suspensie cutanată	*Cutaneous suspension*	Lichid cutanat*	*Cutaneous liquid**
Emulsie cutanată	*Cutaneous emulsion*	Lichid cutanat*	*Cutaneous liquid**

Preparate vaginale *Vaginal preparations*			
Termen complet		**Termen prescurtat**	
română	**engleză**	**română**	**Engleză**
Soluţie vaginală	*Vaginal solution*	Lichid vaginal*	*Vaginal liquid**
Suspensie vaginală	*Vaginal suspension*	Lichid vaginal*	*Vaginal liquid**
Emulsie vaginală	*Vaginal emulsion*	Lichid vaginal*	*Vaginal liquid**
Capsulă (tare) vaginală	Vaginal capsule, hard	Capsulă vaginală*	Vaginal capsule*
Capsulă moale vaginală	Vaginal capsule, soft	Capsulă vaginală*	Vaginal capsule*

Preparate rectale *Rectal preparations*			
Termen complet		**Termen prescurtat**	
română	**engleză**	**română**	**Engleză**
Soluţie rectală	*Rectal solution*	Clismă*	*Enema**
Suspensie rectală	*Rectal suspension*	Clismă*	*Enema**
Emulsie rectală	*Rectal emulsion*	Clismă*	*Enema**

Preparate de inhalat *Preparations for inhalation*			
Termen complet		**Termen prescurtat**	
română	**engleză**	**română**	**Engleză**
Soluţie de inhalat prin nebulizator	*Nebuliser solution*	Inhalant nebulizat*	*Nebuliser liquid**
Suspensie de inhalat prin nebulizator	*Nebuliser suspension*	Inhalant nebulizat*	*Nebuliser liquid**
Emulsie de inhalat prin nebulizator	*Nebuliser emulsion*	Inhalant nebulizat*	*Nebuliser liquid**
Soluţie de inhalat presurizată	*Pressurised inhalation, solution*	Inhalant presurizat*	*Pressurised inhalation**
Suspensie de inhalat presurizată	Pressurised inhalation, suspension	Inhalant presurizat*	Pressurised inhalation*
Emulsie de inhalat presurizată	Pressurised inhalation, emulsion	Inhalant presurizat*	Pressurised inhalation*
Capsulă cu Inhalation powder	Inhalation powder, hard capsule	Inhalation powder*	Inhalation powder*
Pulbere unidose de inhalat	Inhalation powder, pre-dispensed	Inhalation powder*	Inhalation powder*
Soluţie pentru vapori de inhalat	Inhalation vapour, solution	Vapori de inhalat*	Inhalation vapour*
Soluţie pentru vapori de inhalat	Inhalation vapour, solution	Vapori de inhalat*	Inhalation vapour*
Soluţie pentru vapori de inhalat	Inhalation vapour, solution	Vapori de inhalat*	Inhalation vapour*
Soluţie pentru vapori de inhalat	Inhalation vapour, solution	Vapori de inhalat*	Inhalation vapour*
Comprimat pentru vapori de inhalat	Inhalation vapour, tablet	Vapori de inhalat*	Inhalation vapour*
Ointment pentru vapori de inhalat	Inhalation vapour, ointment	Vapori de inhalat*	Inhalation vapour*
Lichid pentru vapori de inhalat	Inhalation vapour, liquid	Vapori de inhalat*	Inhalation vapour*

Preparate traheopulmonare *Tracheopulmonary preparations*			
Termen complet		**Termen prescurtat**	
română	**engleză**	**română**	**Engleză**
Soluţie pentru instilaţie endotraheo-pulmonară	*Endotracheo-pulmonary instillation, solution*	Instilaţie endotraheo-pulmonară*	*Endotracheopulmonary instillation**
Suspensie pentru instilaţie endotraheo-pulmonară	*Endotracheo-pulmonary instillation, suspension*	Instilaţie endotraheo-pulmonară*	*Endotracheopulmonary instillation**

Varia *Miscellaneous*			
Termen complet		**Termen prescurtat**	
română	**engleză**	**română**	**Engleză**
Soluţie pentru modificarea fracţiunilor sanguine	*Solution for blood fraction modification*	Modificator de fracţiuni sanguine*	*Blood fraction modifier**
Soluţie gastroenterală	*Gastroenteral solution*	Lichid gastroenteral*	*Gastroenteral liquid**
Suspensie gastroenterală	*Gastroenteral suspension*	Lichid gastroenteral*	*Gastroenteral liquid**
Emulsie gastroenenterală	*Gastroenteral emulsion*	Lichid gastroenteral*	*Gastroenteral liquid**

* - short term

Medicinal product batches recalled during the 1st quarter of 2014

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Date of recall
1	LUTINUS	Vaginal tablets	100 mg	progesteronum	Ferring GmbH, Germany	0804.215A-1	Quality defect during primary packaging	Recall and destruction	29.11.2013
2	ZENRA	Tablets	5 mg	ramiprilum	Sanofi Winthrop Industrie, France	1L740	Incorrect imprinting of batch number on some packages (batch L234 instead of 1L740)	Recall and destruction	17.01.2014
3	METOCLOPRAMID	Oral drops	7 mg/ml	metoclopramidum	SC Biofarm SA	All batches	Recall of MA no. 6949/2006/01, because of safety grounds, following issuance of European Commission Decision no. C (2013) 9846/ 20.12.2013.	Recall and destruction	21.01.2014
4	NUROFEN RĂCEALĂ ŞI GRIPĂ	tablets (box x 1 blister x 12 tablets)		Combinations	Reckitt Benckiser Healthcare Intern. Ltd., Great Britain	4KK, 6KK, 9KK,10KK,11 KK, AA839, AA851, AB442, AB502, AC177, AC216, AC176, AC800	In accordance with Order of the Minister of Health no. 279/2005, following expiry of the 2-year period as of grant of a new marketing authorisation	Voluntary recall and destruction	21.01.2014
5	NUROFEN RĂCEALĂ ŞI GRIPĂ	tablets (box x 2 blisters x 12 tablets)		Combinations	Reckitt Benckiser Healthcare Intern. Ltd., Great Britain	16HH, 18HH, 16JJ, 10KK, 8KK2, 16KK, 17KK, 23KK, 24KK, 24KK2, AB376, AB371, AC143, AC144, AC274, AC275, AC947, AC500, AC819, AD513, AD530, AE226	In accordance with Order of the Minister of Health no. 279/2005, following expiry of the 2-year period as of grant of a new marketing authorisation	Voluntary recall and destruction	21.01.2014

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Date of recall
6	RHINATHIOL	Syrup for adults	5%	carbocisteinum	Sanof-Aventis, France	Product batches manufactured before 31.03.2012	Change of the trade name from Rhinathiol 5% syrup for adults to Mucosin 750 mg/15 ml cough syrup for adults	Recall and destruction	29.01.2014

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 4th quarter of 2013

During the 4th quarter of 2013, 257 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A01 – Stomatological preparations
A02 - Drugs for acid related disorders
A05 – Bile and liver therapy
A06 – Laxative
A07 – Antidiarrheals, intestinal anti-inflammatory/anti-infective agents
A10 – Drugs used in diabetes
A11 - Vitamins
A12 – Mineral supplements
B01 – Antithrombotic agents
B02 – Antihemorrhagics
B03 – Antianemic preparations
B05 – Blood substitutes and perfusion solutions
B06 – Other haematological agents
C03 – Diuretics
C04 – Peripheral vasodilators
C07 – Beta blocking agents
C08 – Calcium channel blockers
C09 – Agents acting on the renin-angiotensin system
C10 – Lipid modifying agents
D11 – Other dermatological preparations
G03 – Sex hormones and modulators of the genital system
G04 - Urologicals
H05 – Calcium homeostasis
J01 – Antibacterial for systemic use
J02 – Antimycotics for systemic use
J05 – Antivirals for systemic use
J07 – Vaccines
L01 – Antineoplastic agents
L02 – Endocrine therapy
L04 – Imunosuppressants
M01 – Anti-inflammatory and antirheumatic products
M02 – Topical products for joint and muscular pain
N01 - Anesthetics
N02 - Analgezics
N03 - Antiepileptics
N04 – Anti-parkinson drugs

N05 - Psycholeptics
N06 - Psychoanaleptics
N07 – Other nervous system drugs
R01 – Nasal preparations
R03 – Drugs for obstructive airway diseases
R05 – Cough and cold preparations
R06 – Antihistamines for systemic use
S01 - Ophthalmologicals
V09 – Diagnostic radiopharmaceuticals

Medicinal products authorised for marketing during the 4th quarter of 2013

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA number		
	AMINOPLASMAL PAEDIATRIC 100 mg/ml Solution for infusion	Solution for infusion	100 mg/ml	B.Braun Melsungen AG	GERMANY	5895	2013	02
[Tetrakis(2-metoxi-2-metilpropil-1-izocianură) cupru(I)] tetrafluoroborat	TECHNESCAN SESTAMIBI 1 mg Kit for radiopharmaceutical preparations	Kit for radiopharmaceutical preparations	1 mg	MALLINCKRODT MEDICAL B.V.	HOLLAND	5872	2013	01
Abacavir Lamivudine Zidovudine	Abacavir/Lamivudină/Zidovudină Teva 300 mg/150 mg/300 mg Film-coated tablets	Film-coated tablets	300 mg/150 mg/300 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	6002	2013	07
Achillea millefolium D3 Aconitum napellus D3 Atropa belladonna D4 Chamomilla recutita D3 Hepar sulfuris D8 Mercurius solubilis Hahnemanni D8 Symphytum officinale D8 Bellis perennis D2 Calendula officinalis D2 Echinacea D2 Echinacea purpurea D2 Hamamelis virginiana D2 Hypericum perforatum D2 Arnica montana D2	Traumeel S Tablets	Tablets		Biologische Heilmittel Heel GmbH	GERMANY	6012	2013	02
Achillea millefolium TM Aconitum napellus D1 Arnica montana D3 Atropa belladona D1 Bellis perennis TM Calendula officinalis TM Echinacea TM Echinacea purpureaTM Hamamelis virginiana TM Hepar sulfuris D6 Hypericum perforatum D6 Matricaria recutita TM Mercurius solubilis Hahnemanni D6 Symphytum officinale D4	Traumeel S Ointment	Ointment		Biologische Heilmittel Heel GmbH	GERMANY	6013	2013	02

Acetylsalicylic acid	ASPIRIN 500 mg Lozenges	Lozenges	500 mg	Bayer SRL	ROMANIA	6006	2013	05
Acetylsalicylic acid	ASPERAN 75 mg Gastroresistant tablets	Gastroresistant tablets	75 mg	S.C. Slavia Pharm SRL	ROMANIA	6051	2013	01
Acetylsalicylic acid Pseudoephedrine hydrochloride	ASPIRIN COMPLEX HOT DRINK 500 mg/30 mg Granules for oral suspension	Granules for oral suspension	500 mg/30 mg	BAYER S.R.L.	ROMANIA	5914	2013	02
Ibandronic acid	ACID IBANDRONIC MYLAN 150 mg Film-coated tablets	Film-coated tablets	150 mg	GENERIC [UK] Ltd.	GREAT BRITAIN	5892	2013	04
Mycophenolic acid	Acid micofenolic Accord 180 mg Gastroresistant tablets	Gastroresistant tablets	180 mg	Accord Healthcare Limited	GREAT BRITAIN	5943	2013	05
Mycophenolic acid	Acid micofenolic Accord 360 mg Gastroresistant tablets	Gastroresistant tablets	360 mg	Accord Healthcare Limited	GREAT BRITAIN	5944	2013	04
Valproate	CONVULEX 150 mg Gastroresistant soft capsules	Gastroresistant soft capsules	150 mg	GEROT PHARMAZEUTIKA Ges.m.b.H.	AUSTRIA	5919	2013	02
Valproate	CONVULEX 300 mg Gastroresistant soft capsules	Gastroresistant soft capsules	300 mg	GEROT PHARMAZEUTIKA Ges.m.b.H.	AUSTRIA	5920	2013	02
Valproate	CONVULEX 500 mg Gastroresistant soft capsules	Gastroresistant soft capsules		GEROT PHARMAZEUTIKA Ges.m.b.H.	AUSTRIA	5921	2013	02
Zoledronic acid	ACID ZOLEDRONIC ZENTIVA 4 mg/100 ml Solution for infusion	Solution for infusion	4 mg/100 ml	ZENTIVA, k.s.	CZECH REPUBLIC	6032	2013	01
Zoledronic acid	ACID ZOLEDRONIC ZENTIVA 4 mg/100 ml Solution for infusion	Solution for infusion	4 mg/100 ml	ZENTIVA, k.s.	CZECH REPUBLIC	6032	2013	01
Zoledronic acid	ACID ZOLEDRONIC ZENTIVA 4 mg/100 ml Solution for infusion	Solution for infusion	4 mg/100 ml	ZENTIVA, k.s.	CZECH REPUBLIC	6032	2013	01
Zoledronic acid	Acid zoledronic SANTA 4 mg/5 ml Concentrate for solution for infusion	Concentrate for solution for infusion	4 mg/5 ml	S.C. Santa S.A.	ROMANIA	5896	2013	02
Ambazone Monohydrate	FARINGOSEPT LĂMÂIE 10 mg Orodispersible tablets	Orodispersible tablets	10 mg	TERAPIA S.A.	ROMANIA	5904	2013	02
Amoxicillin	AMOXICILINA SANDOZ 250 mg capsule	Capsules	250 mg	S.C. SANDOZ S.R.L	ROMANIA	5937	2013	02

Amoxicillin	AMOXICILINA SANDOZ 500 mg capsule	Capsules	500 mg	S.C. SANDOZ S.R.L	ROMANIA	5938	2013	02
Amoxicillin	AMOXICILINĂ SANDOZ 125 mg/5 ml pulbere pentru suspensie orală	Powder for oral suspension	125 mg/5 ml	S.C. SANDOZ S.R.L	ROMANIA	5939	2013	01
Amoxicillin	AMOXICILINĂ SANDOZ 250 mg/5 ml powder for oral suspension	Powder for oral suspension	250 mg/5 ml	S.C. SANDOZ S.R.L	ROMANIA	5940	2013	01
Atorvastatin	TORVALIPIN 80 mg Film-coated tablets	Film-coated tablets	80 mg	ACTAVIS GROUP PTC ehf.	ICELAND	5855	2013	07
Bicalutamide	NUCLEOMID 50 mg Film-coated tablets	Film-coated tablets	50 mg	S.C. Nucleos Farma SRL	ROMANIA	5915	2013	02
Bicalutamide	NUCLEOMID 150 mg Film-coated tablets	Film-coated tablets	150 mg	S.C. Nucleos Farma SRL	ROMANIA	5916	2013	02
Bimatoprost	BIMATOPROST POLPHARMA 0.3 mg/ml Eye drops, solution	Eye drops, solution	0.3 mg/ml	Pharmaceutical Works POLPHARMA SA	POLLAND	6004	2013	03
Bimatoprost	Bimatoprost Tiefenbacher 0.3 mg/ml Eye drops, solution	Eye drops, solution	0.3 mg/ml	ALFRED E.TIEFENBACHER (GmbH & Co. KG)	GERMANY	6005	2013	04
Bosentan	BOSENTAN ZENTIVA 62.5 mg Film-coated tablets	Film-coated tablets	62.5 mg	ZENTIVA, k.s.	CZECH REPUBLIC	5908	2013	06
Bosentan	BOSENTAN ZENTIVA 125 mg Film-coated tablets	Film-coated tablets	125 mg	ZENTIVA, k.s.	CZECH REPUBLIC	5909	2013	06
Micronized budesonide	FRENOLYN 200 µg Inhalation powder	Inhalation powder	200 µg	MEDOCHEMIE ROMÂNIA SRL	ROMANIA	5989	2013	04
Micronized budesonide	FRENOLYN 400 µg Inhalation powder	Inhalation powder	400 µg	MEDOCHEMIE ROMÂNIA SRL	ROMANIA	5990	2013	04
Candesartan cilexetil	CANDESARTAN AUROBINDO 8 mg tablets	Tablets	8 mg	AUROBINDO PHARMA (Malta) Limited	MALTA	5837	2013	10
Candesartan cilexetil	CANDESARTAN AUROBINDO 16 mg tablets	Tablets	16 mg	AUROBINDO PHARMA (Malta) Limited	MALTA	5838	2013	10
Capecitabine	Capecitabină Dr. Reddy's 500 mg Film-coated tablets	Film-coated tablets	500 mg	Dr. Reddy's Laboratories Romania SRL	ROMANIA	5968	2013	02

Cefadroxil	VALDOCEF 500 mg capsule	Capsules	500 mg	Alkaloid - INT d.o.o.	SLOVENIA	5884	2013	01
Cefadroxil	VALDOCEF 250 mg/5 ml Granules for oral suspension	Granules for oral suspension	250 mg/5 ml	Alkaloid - INT d.o.o.	SLOVENIA	5935	2013	01
Cefixime	XIFIA 400 mg Film-coated tablets	Film-coated tablets	400 mg	INN-FARM d.o.o.	SLOVENIA	5934	2013	03
Cefotaxime	Cefotaxim IPP 1 g Powder for solution for injection/infusion	Powder for solution for injection/infusion	1 g	IPP International Pharma Partners GmbH	GERMANY	5980	2013	03
Cefotaxime	Cefotaxim IPP 2 g Powder for solution for injection/infusion	Powder for solution for injection/infusion	2 g	IPP International Pharma Partners GmbH	GERMANY	5981	2013	03
Ceftazidime	CEFTAMIL 2 g Powder for solution for injection/infusion	Powder for solution for injection/infusion	2 g	Antibiotice S.A.	ROMANIA	5998	2013	03
Celecoxib	ALGOXIB 100 mg capsule	Capsules	100 mg	ZENTIVA k.s.	CZECH REPUBLIC	6041	2013	07
Celecoxib	ALGOXIB 200 mg capsule	Capsules	200 mg	ZENTIVA k.s.	CZECH REPUBLIC	6042	2013	07
Cyclosporin	CIQORIN 25 mg Soft capsules	Soft capsules	25 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	5975	2013	08
Cyclosporin	CIQORIN 50 mg Soft capsules	Soft capsules	50 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	5976	2013	08
Cyclosporin	CIQORIN 100 mg Soft capsules	Soft capsules	100 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	5977	2013	08
Cyclosporin	SANDIMMUN NEORAL 25 mg Soft capsules	Soft capsules	25 mg	NOVARTIS PHARMA GmbH	GERMANY	6023	2013	01
Cyclosporin	SANDIMMUN NEORAL 50 mg Soft capsules	Soft capsules	50 mg	NOVARTIS PHARMA GmbH	GERMANY	6024	2013	01
Cyclosporin	SANDIMMUN NEORAL 100 mg/ml Oral solution	Soft capsules	100 mg/ml	NOVARTIS PHARMA GmbH	GERMANY	6025	2013	01
Cilostazol	CILOSTAZOL LABORMED 100 mg tablets	Tablets	100 mg	Labormed Pharma S.A.	ROMANIA	5961	2013	01
Cilostazol	CILOSTAZOL SANDOZ 100 mg tablets	Tablets	100 mg	S.C. SANDOZ SRL	ROMANIA	5982	2013	10
Bromhexine Hydrochloride	BROMHEXIN BIOFARM 8 mg tablets	Tablets	8 mg	SC BIOFARM SA	ROMANIA	6048	2013	01

Bromhexine Hydrochloride	BROMHEXIN BIOFARM 16 mg tablets	Tablets	16 mg	SC BIOFARM SA	ROMANIA	6049	2013	01
Bupivacaine Hydrochloride	MARCAINE SPINAL 5 mg/ml Solution for injection	Solution for injection	5 mg/ml	AstraZeneca AB	SWEDEN	6019	2013	01
Bupivacaine Hydrochloride	MARCAINE SPINAL HEAVY 5 mg/ml Solution for injection	Solution for injection	5 mg/ml	AstraZeneca AB	SWEDEN	6020	2013	01
Cyclopentolate Hydrochloride	CICLOPENTOLAT ROMPHARM 10 mg/ml Eye drops, solution	Eye drops, solution	10 mg/ml	S.C. Rompharm Company S.R.L	ROMANIA	5867	2013	01
doxorubicin hydrochloride	DOXORUBICINĂ TEVA 2 mg/ml Concentrate for solution for infusion	Concentrate for solution for infusion	2 mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5883	2013	04
Lercanidipine hydrochloride Enalapril maleate	ELERNAP 10 mg/10 mg Film-coated tablets	Film-coated tablets	10 mg/10 mg	KRKA, d.d., Novo mesto	SLOVENIA	5946	2013	12
Lercanidipine hydrochloride Enalapril maleate	ELERNAP 20 mg/10 mg Film-coated tablets	Film-coated tablets	20 mg/10 mg	KRKA, d.d., Novo mesto	SLOVENIA	5947	2013	12
Loperamide hydrochloride Simeticonă	LOSILANE 2 mg/125 mg tablets	Tablets	2 mg/125 mg	Disphar International BV	HOLLAND	5836	2013	18
Memantine hydrochloride	MEMANTINA TORRENT 10 mg/ml Oral solution	Oral solution	10 mg/ml	TORRENT PHARMA SRL	ROMANIA	5835	2013	06
Memantine hydrochloride	MEMANTINA AUROBINDO 10 mg Film-coated tablets	Film-coated tablets	10 mg	AUROBINDO PHARMA (Malta) Limited	MALTA	5857	2013	09
Memantine hydrochloride	POLMATINE 10 mg Film-coated tablets	Film-coated tablets	10 mg	MEDANA PHARMA SA	POLLAND	5868	2013	15
Memantine hydrochloride	POLMATINE 20 mg Film-coated tablets	Film-coated tablets	20 mg	MEDANA PHARMA SA	POLLAND	5869	2013	12
Memantine hydrochloride	POLMATINE 5 mg/dose Oral solution	Oral solution	5 mg/dose	MEDANA PHARMA SA	POLLAND	5870	2013	02
Memantine hydrochloride	MEMANTINA MEDISON PHARMA 10 mg Film-coated tablets	Film-coated tablets	10 mg	Medison Pharma S.R.L	ROMANIA	5893	2013	02

Memantine hydrochloride	MEMANTINA MEDISON PHARMA 20 mg Film-coated tablets	Film-coated tablets	20 mg	Medison Pharma S.R.L	ROMANIA	5894	2013	02
Memantine hydrochloride	MEMANTINA ALVOGEN 5 mg Orodispersible tablets	Orodispersible tablets	5 mg	Alvogen IPCo S.àr.l.	LUXEMBURG	5948	2013	06
Memantine hydrochloride	MEMANTINA ALVOGEN 10 mg Orodispersible tablets	Orodispersible tablets	10 mg	Alvogen IPCo S.àr.l.	LUXEMBURG	5949	2013	04
Memantine hydrochloride	MEMANTINA ATB 10 mg Film-coated tablets	Film-coated tablets	10 mg	ANTIBIOTICE SA	ROMANIA	5950	2013	18
Memantine hydrochloride	MEMANTINA ATB 20 mg Film-coated tablets	Film-coated tablets	20 mg	ANTIBIOTICE SA	ROMANIA	5951	2013	18
Memantine hydrochloride	MEMANTINA ATB 5 mg + 10 mg + 15 mg + 20 mg Film-coated tablets	Film-coated tablets	5 mg + 10 mg + 15 mg + 20 mg	ANTIBIOTICE SA	ROMANIA	5952	2013	01
Memantine hydrochloride	MEMANTINĂ GLENMARK 10 mg Film-coated tablets	Film-coated tablets	10 mg	Glenmark Pharmaceuticals s.r.o.	CZECH REPUBLIC	6007	2013	09
Memantine hydrochloride	MEMANTINĂ GLENMARK 20 mg Film-coated tablets	Film-coated tablets	20 mg	Glenmark Pharmaceuticals s.r.o.	CZECH REPUBLIC	6008	2013	04
Memantine hydrochloride	ZENMEM 10 mg Orodispersible tablets	Orodispersible tablets	10 mg	ZENTIVA k.s.	CZECH REPUBLIC	6016	2013	06
Memantine hydrochloride	ZENMEM 20 mg Orodispersible tablets	Orodispersible tablets	20 mg	ZENTIVA k.s.	CZECH REPUBLIC	6017	2013	06
Memantine hydrochloride	ZENMEM 5 mg+10 mg+15 mg+ 20 mg Orodispersible tablets	Orodispersible tablets	5 mg+10 mg+ 15 mg+20 mg	ZENTIVA k.s.	CZECH REPUBLIC	6018	2013	01
Methadone hydrochloride	MISYO 10 mg/ml Concentrate for oral solution	Concentrate for oral solution	10 mg/ml	INN-FARM d.o.o.	SLOVENIA	5866	2013	04
Metformin hydrochloride	METFORMINĂ GENERICS 500 mg Film-coated tablets	Film-coated tablets	500 mg	GENERICS [UK] Ltd.	GREAT BRITAIN	5958	2013	19
Metformin hydrochloride	METFORMINĂ GENERICS 850 mg Film-coated tablets	Film-coated tablets	850 mg	GENERICS [UK] Ltd.	GREAT BRITAIN	5959	2013	19
Metformin hydrochloride	METFORMINĂ GENERICS 1000 mg Film-coated tablets	Film-coated tablets	1000 mg	GENERICS [UK] Ltd.	GREAT BRITAIN	5960	2013	19

Metformin hydrochloride	METFORMIN BLUEFISH 500 mg Film-coated tablets	Film-coated tablets	500 mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	5962	2013	18
Metformin hydrochloride	METFORMIN BLUEFISH 850 mg Film-coated tablets	Film-coated tablets	850 mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	5963	2013	18
Metformin hydrochloride	METFORMIN BLUEFISH 1000 mg Film-coated tablets	Film-coated tablets	1000 mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	5964	2013	18
Metformin hydrochloride	METFOGAMMA 850 mg Film-coated tablets	Film-coated tablets	850 mg	WÖRWAG PHARMA GmbH & Co. KG	ROMANIA	5993	2013	01
Metformin hydrochloride	METFOGAMMA 1000 mg Film-coated tablets	Film-coated tablets	1000 mg	WÖRWAG PHARMA GmbH & Co. KG	ROMANIA	5994	2013	02
Metformin hydrochloride	MEGUAN 500 mg Film-coated tablets	Film-coated tablets	500 mg	Gedeon Richter România S.A.	ROMANIA	6059	2013	01
Metformin hydrochloride	MEGUAN 850 mg Film-coated tablets	Film-coated tablets	500 mg	Gedeon Richter România S.A.	ROMANIA	6060	2013	01
Naftifine hydrochloride	EXODERIL 10 mg/g Cream	Cream	10 mg/g	SANDOZ GmbH	AUSTRIA	6009	2013	01
Naftifine hydrochloride	EXODERIL 10 mg/ml Cutaneous solution	Cutaneous solution	10 mg/ml	SANDOZ GmbH	AUSTRIA	6010	2013	01
Naltrexone hydrochloride	NALTREXONĂ TORREX 50 mg Film-coated tablets	Film-coated tablets	50 mg	CHIESI PHARMACEUTICALS GmbH	AUSTRIA	6028	2013	04
Procaine hydrochloride	Gerovital H3 100 mg Film-coated tablets	Film-coated tablets	100 mg	SC ZENTIVA SA	ROMANIA	5967	2013	01
Ropivacaine hydrochloride	ROPIVACAINA KABI 2 mg/ml Solution for injection	Solution for injection	2 mg/ml	S.C. FRESENIUS KABI ROMÂNIA S.R.L.	ROMANIA	5862	2013	06
Ropivacaine hydrochloride	ROPIVACAINA KABI 5 mg/ml Solution for injection	Solution for injection	5 mg/ml	S.C. FRESENIUS KABI ROMÂNIA S.R.L.	ROMANIA	5863	2013	03
Ropivacaine hydrochloride	ROPIVACAINA KABI 7.5 mg/ml Solution for injection	Solution for injection	7.5 mg/ml	S.C. FRESENIUS KABI ROMÂNIA S.R.L.	ROMANIA	5864	2013	06
Ropivacaine hydrochloride	ROPIVACAINA KABI 10 mg/ml Solution for injection	Solution for injection	10 mg/ml	S.C. FRESENIUS KABI ROMÂNIA S.R.L.	ROMANIA	5865	2013	06
Xylometazoline hydrochloride	MARESYL 0.5 mg/ml Nasal spray, solution	Nasal spray, solution	0.5 mg/ml	Premier Research GmbH	GERMANY	5906	2013	01

Xylometazoline hydrochloride	MARESYL 1 mg/ml Nasal spray, solution	Nasal spray, solution	1 mg/ml	Premier Research GmbH	GERMANY	5907	2013	01
Xylometazoline hydrochloride Dexpanthenol	SEPTANAZAL 1 mg/50 mg/ml Nasal spray, solution	Nasal spray, solution	1 mg/50 mg/ml	KRKA, d. d., Novo mesto	SLOVENIA	5965	2013	01
Xylometazoline hydrochloride Dexpanthenol	SEPTANAZAL PENTRU COPII 0.5 mg/50 mg/ml Nasal spray, solution	Nasal spray, solution	0.5 mg/50 mg/ml	KRKA, d. d., Novo mesto	SLOVENIA	5966	2013	01
Benzalkonium chloride	CONTRACEPT-M 18,9 mg ovules	Ovules	18,9 mg	S.C. MAGISTRA C&C S.R.L.	ROMANIA	6022	2013	01
Sodium chloride	SER FIZIOLOGIC 9 mg/ml Solvent for parenteral use	Solvent for parenteral use	9 mg/ml	S.C. ANTIBIOTICE S.A.	ROMANIA	5978	2013	03
Desloratadine	DESLORATADINE ARCHIE SAMUEL 5 mg Film-coated tablets	Film-coated tablets	5 mg	Archie Samuel s.r.o.	CZECH REPUBLIC	5910	2013	12
Desogestrel	DIAMILLA 75 micrograms Film-coated tablets	Film-coated tablets	75 micrograms	ACTAVIS GROUP PTC ehf.	ICELAND	5897	2013	03
Desogestrel	AZALIA 75 micrograms Film-coated tablets	Film-coated tablets	75 micrograms	GEDEON RICHTER ROMÂNIA S.A.	ROMANIA	5898	2013	02
Desogestrel Etinilestradiol	CELESTINNE 150 micrograms/ 20 micrograms tablets	Tablets	150 micrograms/ 20 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5874	2013	08
Desogestrel Etinilestradiol	CELESTA 150 micrograms/ 30 micrograms tablets	Tablets	150 micrograms/ 30 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5875	2013	08
Dexketoprofen	Dexketoprofen trometamol Sandoz 12.5 mg Film-coated tablets	Film-coated tablets	12.5 mg	S.C. Sandoz S.R.L	ROMANIA	6046	2013	06
Dexketoprofen	Dexketoprofen trometamol Sandoz 25 mg Film-coated tablets	Film-coated tablets	25 mg	S.C. Sandoz S.R.L	ROMANIA	6047	2013	06
Diclofenac potassium	VOLTFAST 50 mg Powder for oral solution	Powder for oral solution	50 mg	NOVARTIS PHARMA GmbH	GERMANY	5905	2013	04
Azithromycin dihydrate	AZYTER 15 mg/g Eye drops, solution in single-dose container	Eye drops, solution in single-dose container	15 mg/g	LABORATOIRES THEA	FRANCE	5881	2013	01

Anhydrous docetaxel	DOCETAXEL DR. REDDY'S 20 mg/1 ml Concentrate for solution for infusion	Concentrate for solution for infusion	20 mg/1 ml	DR. REDDY'S LABORATORIES ROMÂNIA SRL	ROMANIA	6014	2013	01
Anhydrous docetaxel	DOCETAXEL DR. REDDY'S 80 mg/4 ml Concentrate for solution for infusion	Concentrate for solution for infusion	80 mg/4 ml	DR. REDDY'S LABORATORIES ROMÂNIA SRL	ROMANIA	6015	2013	01
Eptifibatide	EPTIFIBATIDĂ STRIDES 0.75 mg/ml Solution for infusion	Solution for infusion	0.75 mg/ml	STRIDES ARCOLAB INTERNATIONAL Limited	GREAT BRITAIN	5860	2013	01
Eptifibatide	EPTIFIBATIDĂ STRIDES 2 mg/ml Solution for infusion	Solution for infusion	2 mg/ml	STRIDES ARCOLAB INTERNATIONAL Limited	GREAT BRITAIN	5861	2013	01
Erythromycin Isotretinoin	ISOTREXIN 20 mg/g + 0.5 mg/g gel	Gel	20 mg/g + 0.5 mg/g	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	5656	2013	01
Esomeprazole	NEXIUM 40 mg Powder for solution for injection/infusion	Powder for solution for injection/infusion	40 mg	AstraZeneca AB	SWEDEN	6003	2013	02
Omega-3-acid ethyl esters 90	Omega-3-acid ethyl esters EPAX 1000 mg Soft capsules	Soft capsules	1000 mg	Epax AS	NORVEGIA	6040	2013	02
Ethinylestradiol Cyproterone acetate	DIANE-35 0,035 mg/2.0 mg Lozenges	Lozenges	0,035 mg/2.0 mg	BAYER PHARMA AG	GERMANY	5995	2013	01
Exemestane	NUCLEORAN 25 mg Film-coated tablets	Film-coated tablets	25 mg	S.C. Nucleos Farma SRL	ROMANIA	5917	2013	02
Allegren extract (cereal crop pollen): Dactylis glomerata L., Anthoxanthum odoratum L., Lolium perenne L., Poa pratensis L., Phleum pratense L.	ORALAIR 100 IR & 300 IR Sublingual tablets	Sublingual tablets	100 IR & 300 IR	STALLERGENES S.A.	FRANCE	5858	2013	01

Allegren extract (cereal crop pollen): Dactylis glomerata L., Anthoxanthum odoratum L., Lolium perenne L., Poa pratensis L., Phleum pratense L.	ORALAIR 300 IR Sublingual tablets	Sublingual tablets	300 IR	STALLERGENES S.A.	FRANCE	5859	2013	02
Human plasma-derived clotting factor VIII Water for preparations for injection	EMOCLOT 500 IU Powder and solvent for solution for infusion	Powder and solvent for solution for infusion	500 IU	KEDRION S.p.A.	ITALIA	6011	2013	01
Fentanyl	BREAKYL 200 micrograms Buccal soluble film	Buccal soluble film	200 micrograms	MEDA Pharma GmbH & Co. KG	GERMANY	5840	2013	10
Fentanyl	BREAKYL 400 micrograms Buccal soluble film	Buccal soluble film	400 micrograms	MEDA Pharma GmbH & Co. KG	GERMANY	5841	2013	10
Fentanyl	BREAKYL 600 micrograms Buccal soluble film	Buccal soluble film	600 micrograms	MEDA Pharma GmbH & Co. KG	GERMANY	5842	2013	10
Fentanyl	BREAKYL 800 micrograms Buccal soluble film	Buccal soluble film	800 micrograms	MEDA Pharma GmbH & Co. KG	GERMANY	5843	2013	10
Fentanyl	BREAKYL 1200 micrograms Buccal soluble film	Buccal soluble film	1200 micrograms	MEDA Pharma GmbH & Co. KG	GERMANY	5844	2013	10
Fentanyl	BREAKYL Start 200, 400, 600, 800 micrograms Buccal soluble film	Buccal soluble film	200, 400, 600, 800 micrograms	MEDA Pharma GmbH & Co. KG	GERMANY	5845	2013	02
Finasteride	PROSCAR 5 mg Film-coated tablets	Film-coated tablets	5 mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	5885	2013	02
Betamethasone sodium phosphate	OPHTAMESONE 1 mg/ml Eye/ear/nasal drops, solution	Eye/ear/nasal drops, solution	1 mg/ml	DAR AL DAWA PHARMA S.R.L.	ROMANIA	5918	2013	01
Mometasone furoate	MOMETAZONĂ TEVA 50 micrograms/dose Nasal spray, suspension	Nasal spray, suspension	50 micrograms/ dose	Teva Pharmaceuticals S.R.L.	ROMANIA	5945	2013	04
Haloperidol	HALOPERIDOL ARENA 1 mg Tablets	Tablets	1 mg	ARENA GROUP S.A.	ROMANIA	5996	2013	01

Haloperidol	HALOPERIDOL ARENA 2 mg Tablets	Tablets	2 mg	ARENA GROUP S.A.	ROMANIA	5997	2013	01
Ibuprofen	IBUPROFEN ROCKSPRING 600 mg Effervescent granules	Effervescent granules	600 mg	ROCKSPRING HEALTHCARE Limited	GREAT BRITAIN	5850	2013	05
Imatinib	IMATINIB AMOMED 100 mg Film-coated tablets	Film-coated tablets	100 mg	Amomed Pharma GmbH	AUSTRIA	5912	2013	05
Imatinib	IMATINIB AMOMED 400 mg Film-coated tablets	Film-coated tablets	400 mg	Amomed Pharma GmbH	AUSTRIA	5913	2013	05
Imatinib	IMAVEC 100 mg Film-coated tablets	Film-coated tablets	100 mg	Helm AG	GERMANY	5941	2013	04
Imatinib	IMAVEC 400 mg Film-coated tablets	Film-coated tablets	400 mg	Helm AG	GERMANY	5942	2013	03
Irbesartan	IRBESARTAN MEDISON PHARMA 75 mg Film-coated tablets	Film-coated tablets	75 mg	MEDISON PHARMA S.R.L.	ROMANIA	5901	2013	16
Irbesartan	IRBESARTAN MEDISON PHARMA 150 mg Film-coated tablets	Film-coated tablets	150 mg	MEDISON PHARMA S.R.L.	ROMANIA	5902	2013	16
Irbesartan	IRBESARTAN MEDISON PHARMA 300 mg Film-coated tablets	Film-coated tablets	300 mg	MEDISON PHARMA S.R.L.	ROMANIA	5903	2013	16
Ketoprofen	KETOMAG 100 mg Suppositories	Suppositories	100 mg	S.C. MAGISTRA C&C S.R.L.	ROMANIA	6021	2013	01
Ketoprofen	KETOPROFEN ROMPHARM 100 mg/2 ml Solution for injection	Solution for injection	100 mg/2 ml	S.C. Rompharm Company S.R.L.	ROMANIA	6050	2013	02
Levetiracetam	LEVETIRACETAM POLIPHARMA 250 mg Film-coated tablets	Film-coated tablets	250 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	6033	2013	06
Levetiracetam	LEVETIRACETAM POLIPHARMA 500 mg Film-coated tablets	Film-coated tablets	500 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	6034	2013	08
Levetiracetam	LEVETIRACETAM POLIPHARMA 750 mg Film-coated tablets	Film-coated tablets	750 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	6035	2013	06

Levetiracetam	LEVETIRACETAM POLIPHARMA 1000 mg Film-coated tablets	Film-coated tablets	1000 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	6036	2013	07
Levofloxacin	LEVOFLOXACINĂ MYLAN 250 mg/50 ml Solution for infusion	Solution for infusion	250 mg/50 ml	MYLAN S.A.S	FRANCE	5899	2013	07
Levofloxacin	LEVOFLOXACINĂ MYLAN 500 mg/100 ml Solution for infusion	Solution for infusion	500 mg/100 ml	MYLAN S.A.S	FRANCE	5900	2013	07
Losartan Potassium-Hydrochlorothiazide	HYZAAR 50 mg/12.5 mg Film-coated tablets	Film-coated tablets	50 mg/12.5 mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	6030	2013	16
Losartan Potassium-Hydrochlorothiazide	FORTZAAR 100 mg/25 mg Film-coated tablets	Film-coated tablets	100 mg/25 mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	6031	2013	14
Dimethindene maleate	FENISTIL GEL 1 mg/g gel	Gel	1 mg/g	NOVARTIS CONSUMER HEALTH GmbH	GERMANY	5979	2013	01
Memantine	MEMANTINĂ TERAPIA 10 mg Film-coated tablets	Film-coated tablets	10 mg	TERAPIA SA	ROMANIA	5846	2013	20
Memantine	MEMANTINĂ TERAPIA 20 mg Film-coated tablets	Film-coated tablets	20 mg	TERAPIA SA	ROMANIA	5847	2013	15
Memantine	MEMANTINĂ RANBAXY 10 mg Film-coated tablets	Film-coated tablets	10 mg	RANBAXY (U.K.) Limited	GREAT BRITAIN	5848	2013	06
Memantine	MEMANTINĂ RANBAXY 20 mg Film-coated tablets	Film-coated tablets	20 mg	RANBAXY (U.K.) Limited	GREAT BRITAIN	5849	2013	08
Memantine	COGNOMEM 10 mg Film-coated tablets	Film-coated tablets	10 mg	ZENTIVA k.s.	CZECH REPUBLIC	6056	2013	13
Memantine	COGNOMEM 20 mg Film-coated tablets	Film-coated tablets	20 mg	ZENTIVA k.s.	CZECH REPUBLIC	6057	2013	13
Memantine	COGNOMEM 5 mg/released dose, Oral solution	Oral solution	5 mg/released dose	ZENTIVA k.s.	CZECH REPUBLIC	6058	2013	03
anhydrous meropenem	MEROPENEM ACTAVIS 500 mg Powder for solution for injection/infusion	Powder for solution for injection/infusion	500 mg	ACTAVIS GROUP PTC ehf.	ICELAND	5932	2013	02
anhydrous meropenem	MEROPENEM ACTAVIS 1 g Powder for solution for	Powder for solution for injection/infusion	1 g	ACTAVIS GROUP PTC ehf.	ICELAND	5933	2013	02

	injection/infusion							
anhydrous meropenem	MEROPENEM TEVA 500 mg Powder for solution for injection/infusion	Powder for solution for injection/infusion	500 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	5973	2013	02
anhydrous meropenem	MEROPENEM TEVA 1000 mg Powder for solution for injection/infusion	Powder for solution for injection/infusion	1000 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	5974	2013	02
Metamizole Sodium Monohydrate	MIMETANAL 500 mg/ml Oral drops, solution	Oral drops, solution	500 mg/ml	MIDAS PHARMA GmbH	GERMANY	5871	2013	04
Methotrexate	Metoject PEN 7.5 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	7.5 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5922	2013	11
Methotrexate	Metoject PEN 10 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	10 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5923	2013	11
Methotrexate	Metoject PEN 12.5 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	12.5 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5924	2013	11
Methotrexate	Metoject PEN 15 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	15 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5925	2013	01
Methotrexate	Metoject PEN 15 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	15 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5925	2013	01
Methotrexate	Metoject PEN 15 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	15 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5925	2013	01
Methotrexate	Metoject PEN 15 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	15 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5925	2013	01
Methotrexate	Metoject PEN 15 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	15 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5925	2013	01

Methotrexate	Metoject PEN 15 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	15 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5925	2013	01
Methotrexate	Metoject PEN 15 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	15 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5925	2013	01
Methotrexate	Metoject PEN 15 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	15 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5925	2013	01
Methotrexate	Metoject PEN 15 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	15 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5925	2013	11
Methotrexate	Metoject PEN 17.5 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	17.5 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5926	2013	11
Methotrexate	Metoject PEN 20 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	20 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5927	2013	11
Methotrexate	Metoject PEN 22.5 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	22.5 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5928	2013	11
Methotrexate	Metoject PEN 25 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	25 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5929	2013	01
Methotrexate	Metoject PEN 25 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	25 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5929	2013	11
Methotrexate	Metoject PEN 27.5 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	27.5 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5930	2013	11
Methotrexate	Metoject PEN 30 mg Solution for injection in pre-filled pen	Solution for injection in pre-filled pen	30 mg	medac Gesellschaft für klinische Spezialpräparate mbH	GERMANY	5931	2013	11
Milrinone	UNACOR 1 mg/ml Concentrate for solution for infusion	Concentrate for solution for infusion	1 mg/ml	Pharmaselect International Beteiligungs GmbH	AUSTRIA	5873	2013	02
Mirtazapine	MIRTAZAPIN ARENA 15 mg Film-coated tablets	Film-coated tablets	15 mg	Arena Group S.A.	ROMANIA	6037	2013	01

Mirtazapine	MIRTAZAPIN ARENA 30 mg Film-coated tablets	Film-coated tablets	30 mg	Arena Group S.A.	ROMANIA	6038	2013	01
Mirtazapine	MIRTAZAPIN ARENA 45 mg Film-coated tablets	Film-coated tablets	45 mg	Arena Group S.A.	ROMANIA	6039	2013	01
Nitric oxide	NEOPHYR 225 ppm mol/mol Compressed medical gas	Compressed medical gas	225 ppm mol/mol	SOL S.p.A.	ITALIA	5877	2013	01
Nitric oxide	NEOPHYR 450 ppm mol/mol Compressed medical gas	Compressed medical gas	450 ppm mol/mol	SOL S.p.A.	ITALIA	5878	2013	01
Nitric oxide	NEOPHYR 1000 ppm mol/mol Compressed medical gas	Compressed medical gas	1000 ppm mol/mol	SOL S.p.A.	ITALIA	5879	2013	01
Montelukast	MONKASTA 4 mg Chewable tablets	Chewable tablets	4 mg	KRKA d.d. Novo mesto	SLOVENIA	5970	2013	15
Montelukast	MONKASTA 5 mg Chewable tablets	Chewable tablets	5 mg	KRKA d.d. Novo mesto	SLOVENIA	5971	2013	15
Montelukast	MONKASTA 10 mg Film-coated tablets	Film-coated tablets	10 mg	KRKA d.d. Novo mesto	SLOVENIA	5972	2013	15
Moxifloxacine	MOFINACIN 400 mg Film-coated tablets	Film-coated tablets	400 mg	ALVOGEN IPCo S.à.r.l.	LUXEMBURG	5888	2013	03
Monoxidine	MONOXIDINE MYLAN 0.2 mg Film-coated tablets	Film-coated tablets	0.2 mg	GENERICS [UK] Ltd	GREAT BRITAIN	5889	2013	07
Monoxidine	MONOXIDINE MYLAN 0.3 mg Film-coated tablets	Film-coated tablets	0.3 mg	GENERICS [UK] Ltd	GREAT BRITAIN	5890	2013	07
Monoxidine	MONOXIDINE MYLAN 0.4 mg Film-coated tablets	Film-coated tablets	0.4 mg	GENERICS [UK] Ltd	GREAT BRITAIN	5891	2013	07
Monoxidine	PHYSIOTENS 0.2 mg Film-coated tablets	Film-coated tablets	0.2 mg	ABBOTT LABORATORIES GmbH	GERMANY	5991	2013	03
Monoxidine	PHYSIOTENS 0.4 mg Film-coated tablets	Film-coated tablets	0.4 mg	ABBOTT LABORATORIES GmbH	GERMANY	5992	2013	03
Amlodipine/Olmesartan Medoxomil	SEVIKAR 20 mg/5 mg Film-coated tablets	Film-coated tablets	20 mg/5 mg	TERAPIA S.A.	ROMANIA	5953	2013	11
Amlodipine/Olmesartan Medoxomil	SEVIKAR 40 mg/5 mg Film-coated tablets	Film-coated tablets	40 mg/5 mg	TERAPIA S.A.	ROMANIA	5954	2013	11

Amlodipine/Olmesartan Medoxomil	SEVIKAR 40 mg/10 mg Film-coated tablets	Film-coated tablets	40 mg/10 mg	TERAPIA S.A.	ROMANIA	5955	2013	11
Ondansetron	OSETRON 4 mg Film-coated tablets	Film-coated tablets	4 mg	Dr. Reddy's Laboratories Romania S.R.L.	ROMANIA	6026	2013	01
Ondansetron	OSETRON 8 mg Film-coated tablets	Film-coated tablets	8 mg	Dr. Reddy's Laboratories Romania S.R.L.	ROMANIA	6027	2013	01
Pantoprazole	AZATOL 20 mg Gastroresistant tablets	Gastroresistant tablets	20 mg	SC Neola Pharma SRL	ROMANIA	5956	2013	06
Pantoprazole	AZATOL 40 mg Gastroresistant tablets	Gastroresistant tablets	40 mg	SC Neola Pharma SRL	ROMANIA	5957	2013	06
Pantoprazole	PANTOPRAZOL TERAPIA 20 mg Gastroresistant tablets	Gastroresistant tablets	20 mg	Terapia S.A.	ROMANIA	6062	2013	03
Paracetamole	PARACETAMOL ACTAVIS 10 mg/ml Solution for infusion	Solution for infusion	10 mg/ml	ACTAVIS GROUP PTC ehf	ICELAND	5854	2013	03
Paracetamole	PANADOL OPTIZORB 500 mg Film-coated tablets	Film-coated tablets	500 mg	GlaxoSmithKline Export Limited, GlaxoSmithKline Consumer Healthcare	GREAT BRITAIN	5936	2013	09
Paricalcitole	PARICALCITOL TEVA 5 micrograms/ml Solution for injection	Solution for injection	5 micrograms/ml	Teva Pharmaceuticals S.R.L.	ROMANIA	5969	2013	08
Sodium picosulfate Light magnesium oxide Anhydrous citric acid	CitraFleet Powder for oral solution	Powder for oral solution		Laboratorios Casen-Fleet, S.L.U.	SPANIA	5876	2013	07
Capsular polysaccharide of Haemophilus influenzae type B conjugated with tetanus anatoxin Suspension Diphtheria anatoxin Tetanus anatoxin Pertussis anatoxin Filamentous haemagglutinin Pertactin Poliovirus type 1 inactivated Poliovirus type 2 inactivated	Infanrix-IPV+Hib Powder and suspension for suspension for injection	Powder and suspension for suspension for injection		GLAXOSMITHKLINE BIOLOGICALS SA	BELGIA	5880	2013	21

Poliovirus type 3 inactivated								
Risedronate Sodium	RISEDRONAT AUROBINDO 35 mg Film-coated tablets	Film-coated tablets	35 mg	Aurobindo Pharma (Malta) Limited	MALTA	6029	2013	06
Risperidone	RISON 2 mg Film-coated tablets	Film-coated tablets	2 mg	Actavis Group Hf.	ICELAND	5985	2013	08
Risperidone	RISON 3 mg Film-coated tablets	Film-coated tablets	3 mg	Actavis Group Hf.	ICELAND	5986	2013	08
Risperidone	RISON 4 mg Film-coated tablets	Film-coated tablets	4 mg	Actavis Group Hf.	ICELAND	5987	2013	08
Rosuvastatin	ROVASTAMED 5 mg Film-coated tablets	Film-coated tablets	5 mg	Medochemie Ltd.	CIPRU	6052	2013	09
Rosuvastatin	ROVASTAMED 10 mg Film-coated tablets	Film-coated tablets	10 mg	Medochemie Ltd.	CIPRU	6053	2013	09
Rosuvastatin	ROVASTAMED 20 mg Film-coated tablets	Film-coated tablets	20 mg	Medochemie Ltd.	CIPRU	6054	2013	09
Rosuvastatin	ROVASTAMED 40 mg Film-coated tablets	Film-coated tablets	40 mg	Medochemie Ltd.	CIPRU	6055	2013	09
Rupatadine	TAMALIS 10 mg Tablets	Tablets	10 mg	J. Uriach & Cía., S.A.	SPANIA	5999	2013	08
Rupatadine	TAMALIS 1 mg/ml Oral solution	Oral solution	1 mg/ml	J. Uriach & Cía., S.A.	SPANIA	6000	2013	01
Silver sulfadiazine	CICATROL 10 mg/g Cutaneous paste	Cutaneous paste	10 mg/g	ANTIBIOTICE SA	ROMANIA	5988	2013	02
Atropine Sulphate	SULFAT DE ATROPINĂ TAKEDA 1 mg/ml Solution for injection	Solution for injection	1 mg/ml	TAKEDA GmbH	GERMANY	6061	2013	02
Brimonidine Tartrate Timolol	COMBIGAN 2 mg/ml + 5 mg/ml Eye drops, solution	Eye drops, solution	2 mg/ml + 5 mg/ml	ALLERGAN PHARMACEUTICALS IRELAND	IRLANDA	6001	2013	02
Telmisartan Hydroclortiazide	Tezeo HCT 40 mg/12.5 mg Tablets	Tablets	40 mg/12.5 mg tablets	ZENTIVA, k.s.	CZECH REPUBLIC	5851	2013	07
Telmisartan Hydroclortiazide	Tezeo HCT 80 mg/12.5 mg Tablets	Tablets	80 mg/12.5 mg tablets	ZENTIVA, k.s.	CZECH REPUBLIC	5852	2013	07
Telmisartan Hydroclortiazide	Tezeo HCT 80 mg/25 mg Tablets	Tablets	80 mg/25 mg tablets	ZENTIVA, k.s.	CZECH REPUBLIC	5853	2013	07
Telmisartan	TELMARK PLUS	Tablets	80 mg/12.5 mg		CZECH	5886	2013	07

Hydroclortiazide	80 mg/12.5 mg Tablets			GLENMARK PHARMACEUTICALS s.r.o.	REPUBLIC			
Telmisartan Hydroclortiazide	TELMARK PLUS 80 mg/25 mg Tablets	Tablets	80 mg/25 mg	GLENMARK PHARMACEUTICALS s.r.o.	CZECH REPUBLIC	5887	2013	07
Tetrabenazine	TETMODIS 25 mg Tablets	Tablets	25 mg	AOP Orphan Pharmaceuticals AG	AUSTRIA	5839	2013	01
Topotecan	TOPOTECAN MEDISON PHARMA 4 mg Powder for concentrate for solution for infusion	Powder for concentrate for solution for infusion	4 mg	MEDISON PHARMA S.R.L.	ROMANIA	5882	2013	01
Topotecan	TOPOTECAN KABI 1 mg/ml Concentrate for solution for infusion	Concentrate for solution for infusion	1 mg/ml	Fresenius Kabi Oncology Plc.	GREAT BRITAIN	6043	2013	04
Torasemide	TORASEMIDĂ TEVA 5 mg tablets	Tablets	5 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	5983	2013	06
Torasemide	TORASEMIDĂ TEVA 10 mg tablets	Tablets	10 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	5984	2013	06
Voriconazole	VORICONAZOL TEVA 50 mg Film-coated tablets	Film-coated tablets	50 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	6044	2013	23
Voriconazole	VORICONAZOL TEVA 200 mg Film-coated tablets	Film-coated tablets	200 mg	Teva Pharmaceuticals S.R.L.	ROMANIA	6045	2013	23
Zidovudine	RETROVIR 10 mg/ml Oral solution	Oral solution	10 mg/ml	ViiV Healthcare UK Limited	GREAT BRITAIN	5911	2013	02

Medicinal products authorised through centralised procedure by the EMA for which a marketing price was established in Romania during the 4th quarter of 2013

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA number		
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC HOSPIRA 4 mg/100 ml	Solution for infusion	4 mg/100 ml	HOSPIRA UK LIMITED	GREAT BRITAIN	800	2013	01
ARIPIPRAZOLUM	ABILIFY MAINTENA 400mg	Prolonged-release powder and solvent for solution for injection	400mg	OTSUKA PHARMACEUTICAL EUROPE LTD.	GREAT BRITAIN	882	2013	01
AVANAFILUM	SPEDRA 50mg	Tablets	50mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBURG S.A.	LUXEMBURG	841	2013	03
AVANAFILUM	SPEDRA 200mg	Tablets	200mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBURG S.A.	LUXEMBURG	841	2013	03
AVANAFILUM	SPEDRA 100mg	Tablets	100mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBURG S.A.	LUXEMBURG	841	2013	04
CAPECITABINUM	ECANSYA 500mg	Film-coated tablets	500mg	KRKA D.D.	SLOVENIA	763	2013	06
COMBINATIONS (FLUTICASONUM+ VILANTEROLUM)	RELVAR ELLIPTA 92micrograms/22micrograms	Inhalation powder	92micrograms+ 22micrograms	GLAXO GROUP LTD.	GREAT BRITAIN	886	2013	01