THE GOVERNMENT OF ROMANIA

EMERGENCY ORDINANCE
amending certain healthcare regulations

Having regard to Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use as well as provisions 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,

Taking into account Romania's obligation to observe deadlines for transposition of Directive 2010/84/EU and Directive 2010/53/EU into national law, namely by 21 July 2012 and 27 August 2012, respectively,

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

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

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

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

Taking into account that failure to adopt emergency measures contained in this bill may affect the rights of individuals, who may refer to national courts under the principle of the direct effect of directives, where harm has been done in result of non-compliance with European Union legislation on transplantation and pharmacovigilance activities,

To ensure equal public access to permanent and quality healthcare as well in localities where hospitals have been closed down and turned into multifunctional centres as legal entities as well as to responsibly implicate local authorities in the operation of such public institutions for safeguarding public healthcare,

Given the mandatory introduction in August 2012 of the national health card and the positive effects generated by this tool in management of financial resources allocated to the healthcare system,

For consistent regulation and adoption of immediate measures to ensure compliance with commitments of the Romanian Government in negotiations for loan agreements with financial institutions as regards the general consolidated budget deficit for 2012,

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

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

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

The Government of Romania hereby adopts this Emergency Ordinance.

29. **Article 695 (13) is deleted.**

30. Under Article 695, a new point (28[1]) is inserted after point 28, as follows:

"28[1]. Pharmacovigilance issues:

a) *Risk management system:* a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions;

b) *Risk management plan:* a detailed description of the risk management system;

c) *Pharmacovigilance system:* a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in Chapter X and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance;

d) *Pharmacovigilance system master file:* A detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products."

31**. Points k) and o) under Article 702 (4) are amended as follows:**

"k) A summary of the applicant's pharmacovigilance system which shall include the following elements:

— proof that the applicant has at his disposal a qualified person responsible for pharmacovigilance,

— the Member States in which the qualified person resides and carries out his/her tasks,

— the contact details of the qualified person,

— a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Chapter IX,

— a reference to the address of the location where the pharmacovigilance system master file for the medicinal product is kept.',

.....

o) Copies of the following:

— any authorisation, obtained in another Member State or in a third country, to place the medicinal product on the market, a summary of the safety data including the data contained in the periodic safety update reports, where available, and suspected adverse reactions reports, together with a list of those Member States in which an application for authorisation submitted in accordance with Directive 20001/83/EC is under examination;

— the summary of the product characteristics proposed by the applicant in accordance with Article 708 or approved by the National Agency for Medicines and Medical Devices in accordance with Article 726 and the package leaflet proposed in accordance with Article 769 or approved by the National Agency for Medicines and Medical Devices in accordance with Article 771;

— details of any decision to refuse authorisation, whether in the Union or in a third country, and the reasons for such a decision.

32. **A new point is inserted, k[1]) under Art. 702 (4), reading:**

"k[1]) The risk management plan describing the risk management system which the applicant will introduce for the medicinal product concerned, together with a summary thereof."

33. **Article 702 (4) q) is deleted.**

34. **Under Article 702, a new paragraph, (6), is inserted after (5), reading:**

"(6) The risk management system referred to in point (4) k[1]) shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data The information referred to in subparagraph (4) shall be updated where and when appropriate."

35. **Article 708 is amended as follows:**

"Art. 708. - (1) The Summary of Product Characteristics includes the following data, in this order:

1. Name of the medicinal product followed by Strength and Pharmaceutical form;

2. Qualitative and quantitative composition in terms of the active substance(s) and excipients, knowledge of which are essential for proper administration of the medicinal product; the usual common name or the exact scientific designation are used;

3. Pharmaceutical form;

4. Clinical particulars:

4.1. Therapeutic indications;

4.2. Posology and method of administration for adults and the paediatric population, as appropriate;

4.3. contraindications;

4.4. Special warnings and precautions for use and, for immunological medicinal products, any specific warnings for healthcare staff concerning the handling and administration of the product, together with precautions for use for the patient;

4.5. Interaction with other medicinal products and other forms of interaction;

4.6. Fertility, pregnancy and lactation;

4.7. Effects on ability to drive and use machines;

4.8. Undesirable effects;

4.9. Overdose (symptoms, emergency procedures, antidotes);

5. Pharmacological properties:

5.1. Pharmacodynamic properties;

5.2. Pharmacokinetic properties;

5.3. Preclinical safety data;

6. Pharmaceutical particulars:

6.1. List of excipients;

6.2. Incompatibilities;

6.3. Shelf life, after dilution or reconstitution or after first opening included, where necessary;

6.4. Special precautions for storage;

6.5. Nature and contents of container;

6.6. Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product, where needed;

7. Marketing authorisation holder;

8. Marketing authorisation number(s);

9. Date of first authorisation/renewal of the authorisation;

10. Date of revision of the text;

11. Dosimetry, full details of internal radiation dosimetry for radiopharmaceuticals;

12. Instructions for preparation of radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform to its specifications.

(2) For authorisations under Article. 704, those parts of the Summary of Product Characteristics of the reference medicinal product related to indications or pharmaceutical forms still under patent at the time when a generic is placed on the market should not be included.

(3) For medicinal products included on the list referred to in Article 23 of Regulation (EC) No 726/2004, of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for

human and veterinary use and establishing a European Medicines Agency, the summary of product characteristics shall include the statement: “This medicinal product is subject to additional monitoring”. This statement shall be preceded by the black symbol referred to in Article 23 of Regulation (EC) 726/2004 and this statement shall be preceded by the black symbol referred to in Article 23 of. For all medicinal products, a standard text shall be included expressly asking healthcare professionals to report any suspected adverse reaction to the National Agency for Medicines and Medical Devices, in accordance with Article 819^1 (1). Different ways of reporting, including electronic reporting, shall be available in compliance with the first paragraph of Article 819^1 (1).”

36. **Article 720 (1) is amended as follows:**

(1) Provisions of art. 697 a) and b), art. 700 (1), art. 709, art. 722 (1), art. 724, 725, 728, 730, 731, 748-761, 780-796, 812-820^1, art. 823 (1) and (3), art. 824, 828, 829, 830, 839, 840, 842, art. 843 (2) and art. 846, as well as Principles and guidelines for good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, approved through order of the minister of health, also apply to authorisations for herbal medicinal products for traditional use.”

37. **Article 722 is amended as follows:**

"Art. 722. - (1) The National Agency for Medicines and Medical Devices shall take every appropriate measure to ensure that the procedure for granting a marketing authorisation is completed a maximum of 210 days after submission of a valid application; applications for marketing authorisations in Romania and one or several Member States in respect of the same medicinal product shall be submitted in accordance to Articles 736-747.

(2) Where the National Agency for Medicines and Medical Devices notes that another marketing authorisation application for the same medicinal product is being examined by another Member State, the National Medicines Agency shall decline to assess the application and shall advise the applicant that Articles 736-747 apply.”

38. **Article 723 is amended as follows:**

"Art. 723. - “Where the National Agency for Medicines and Medical Devices is informed in accordance with Article 702 (4), o), that another Member State has authorised a medicinal product which is the subject of a marketing authorisation application in Romania, the National Medicines Agency shall reject the application unless it was submitted in compliance with Articles 736-747.”

39. Paragraphs (3) and (4) of Article 726 are amended as follows:

"(3) The National Agency for Medicines and Medical Devices shall, without delay, make publicly available the marketing authorisation together with the package leaflet, the summary of the product characteristics and any conditions established in accordance with 726^1, 727 and 727^1, together with any deadlines for the fulfilment of those conditions for each medicinal product which they have authorised.

(4) The National Agency for Medicines and Medical Devices shall draw up an assessment report and make comments on the file as regards the results of the pharmaceutical and pre-clinical tests, the clinical trials, the risk management system and the pharmacovigilance system of the medicinal product concerned. The assessment report shall be updated whenever new information becomes available which is important for the evaluation of the quality, safety or efficacy of the medicinal product concerned. The National Agency for Medicines and Medical Devices shall make the assessment report publicly accessible without delay, together with the reasons for their opinion, after deletion of any information of a commercially confidential nature. The justification shall be provided separately for each indication applied for. The public assessment report shall include a summary written in a manner that is understandable to the public. The summary shall contain, in particular, a section relating to the conditions of use of the medicinal product.”

40. **Article 726 (5) is amended.**

41. A new article, Article 726^1 is inserted Article 726, as follows:

"Art. 726^1. - (1) In addition to the provisions laid down in Article 724, a marketing authorisation for a medicinal product may be granted subject to one or more of the following conditions:

a) to take certain measures for ensuring the safe use of the medicinal product to be included in the risk management system;

b) to conduct post-authorisation safety studies;

c) to comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than those referred to in Chapter X;

d) any other conditions or restrictions with regard to the safe and effective use of the medicinal product;

e) the existence of an adequate pharmacovigilance system;

f) conduct of post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed; Such an obligation to conduct such studies shall be based on the delegated acts adopted pursuant to Article 22b of Directive *2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use*, while taking into account the scientific guidance referred to in Article 820^1.

(2) The marketing authorisation shall lay down deadlines for the fulfilment of conditions specified under (1), where necessary."

42. **Article 727 is amended as follows:**

"Art. 727. - (1) In exceptional circumstances and following consultation with the applicant, the marketing authorisation may be granted, subject to certain conditions, in particular relating to the safety of the medicinal product, notification to the National Agency for Medicines and Medical Devices of any incident relating to its use, and action to be taken.

(2) The marketing authorisation may be granted only when the applicant can show that he is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, for objective, verifiable reasons and must be based on one of the grounds set out in Analytical, pharmacotoxicological and clinical norms and protocols in respect of the testing of medicinal products, approved through order of the minister of health; continuation of the marketing authorisation shall be linked to the annual reassessment of these conditions."

43. Three new articles, 727^1-727^3, are inserted after Article 727, as follows:

"Art. 727^1. - (1) After the granting of a marketing authorisation, the National Agency for Medicines and Medical Devices may decide to impose an obligation on the marketing authorisation holder:

a) to conduct a post-authorisation safety study if there are concerns about the risks of an authorised medicinal product. If the same concerns apply to more than one medicinal product, the National Agency for Medicines and Medical Devices shall, following consultation with the Pharmacovigilance Risk Assessment Committee, recommend the marketing authorisation holders concerned to conduct a joint post-authorisation safety study;

b) to conduct a post-authorisation efficacy study when the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly. The obligation to conduct the post-authorisation efficacy study shall be based on the delegated acts adopted pursuant to Article 22b of Directive 2010/84/EU, while taking into account the scientific guidance referred to in Article 820^1. The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and timeframe for submission and conduct of the study.

(2) The National Agency for Medicines and Medical Devices shall provide the marketing authorisation holder with an opportunity to present written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.

(3) On the basis of the written observations submitted by the marketing authorisation holder, the National Agency for Medicines and Medical Devices shall withdraw or confirm the obligation. Where The National Agency for Medicines and Medical Devices confirms the obligation, the marketing authorisation shall be varied to include the obligation as a condition of the marketing authorisation and the risk management system shall be updated accordingly.

Art. 727^2. - To supplement provisions of articles 726^1 and 727^1, the National Agency for Medicines and Medical Devices pursues application by marketing authorisation holders of delegated acts adopted by the European Commission in order to determine the situations in which post-authorisation efficacy studies may be required.

Art. 727^3. - (1) The marketing authorisation holder shall incorporate any conditions referred to in Articles 726^1, 727 or 727^1, as the case may be, in his risk management system.

(2) The National Agency for Medicines and Medical Devices shall inform the Agency of the marketing authorisations that they have granted subject to conditions pursuant to Articles 726^1, 727 or 727^1, as appropriate."

44. **Article 728 is amended as follows:**

"Art. 728. - (1) After a marketing authorisation has been granted, the marketing authorisation holder shall, in respect of the methods of manufacture and control provided for in Article 702 (4), e) and i), take account of scientific and technical progress and introduce any changes that may be required to enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods; those changes shall be subject to the approval of the National Agency for Medicines and Medical Devices.

(2) The marketing authorisation holder shall forthwith provide the National Agency for Medicines and Medical Devices with any new information which might entail the amendment of the particulars or documents referred to in Article 702 (4), art. 704, 705, 706. 708 or art. 740 or the Analytical, pharmacotoxicological and clinical norms and protocols in respect of the testing of medicinal products, approved through order of the minister of health. The marketing authorisation holder shall forthwith inform the National Agency for Medicines and Medical Devices of any prohibition or restriction imposed by the national competent authority of any country in which the medicinal product is marketed and of any other new information which might influence the evaluation of the benefits and risks of the medicinal product concerned. The information shall include both positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation.

(3) The marketing authorisation holder shall ensure that the product information is kept up to date with the current scientific knowledge, including the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) 726/2004.

(4) In order to be able to continuously assess the risk- benefit balance, the National Agency for Medicines and Medical Devices may at any time ask the marketing authorisation holder to forward data demonstrating that the risk-benefit balance remains favourable. The marketing authorisation holder shall answer fully and promptly any such request. The National Agency for Medicines and Medical Devices may at any time ask the marketing authorisation holder to submit a copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit the copy at the latest 7 days after receipt of the request."

45. **Paragraphs (2) and (5) of Art. 730 are amended as follows:**

"(2) The marketing authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the National Agency for Medicines and Medical Devices, if this is the issuer of the authorisation; to this end, at least 9 months before the marketing authorisation ceases to be valid in accordance with paragraph (1), the marketing authorisation holder shall provide the National Agency for Medicines and Medical Devices with a consolidated version of the file in respect of quality, safety and efficacy, including the evaluation of data contained in suspected adverse reactions reports and periodic safety update reports submitted in accordance with Chapter X, as well as all variations introduced since the marketing authorisation was granted.

.....

(5) Once renewed, the marketing authorisation shall be valid for an unlimited period, unless the National Agency for Medicines and Medical Devices decide, authority decides, on justified grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, to proceed with one additional five-year renewal in accordance with paragraph (2)."

46. Under Title XVII, Chapter III, the title of Section 5 "Mutual recognition and decentralised procedure" is deleted.

47. **Article 735 is amended as follows:**

"Art. 735. - (1) The National Agency for Medicines and Medical Devices Agency shall appoint one representative and one alternate for a renewable period of three years to take part in the Group for the coordination of these procedures. The representative in the Coordination group of the National Agency for Medicines and Medical Devices may be accompanied by experts. For the fulfilment of its tasks, the Coordination group shall rely on the scientific and regulatory resources available to national competent authorities. The National Agency for Medicines and Medical Devices shall monitor the level of expertise of the evaluations carried out and facilitate the activities of nominated Coordination group members and experts. As regards transparency and the independence of its members, Article 63 of Regulation (EC) No 726/2004 shall apply to the Coordination group.

(2) The Coordination group fulfils the following tasks:

a) the examination of any question relating to a marketing authorisation of a medicinal product in two or more Member States in accordance with the procedures laid down in section 5;

b) the examination of questions related to the pharmacovigilance of medicinal products authorised by the Member States, in accordance with Articles 819^{3}, 819^{5}, 819^{7}, 819^{11} and 819^{17};

c) the examination of questions relating to variations of marketing authorisations granted by the Member States, in accordance with Article 743.

(3) The representative of the National Agency for Medicines and Medical Devices in the Coordination group shall ensure that there is appropriate coordination between the tasks of that group and the work of national competent authorities.

(4) Save where otherwise provided for in this law, the Member States represented within the Coordination group shall use their best endeavours to reach a position by consensus on the action to be taken. If such a consensus cannot be reached, the position of the majority of the Member States represented within the Coordination group shall prevail.

(5) The representative of the National Agency for Medicines and Medical Devices in the Coordination group shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy.

48. The title of a new section, section 5, is inserted after Article 735, reading:

"SECTION 5
Mutual recognition and decentralised procedure"

49. Article 739 is amended as follows:

"Art. 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, in specific cases where the interests of the European Union are involved, the National Agency for Medicines and Medical Devices, Member States, the Commission, the applicant or the marketing authorisation holder shall 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 National Agency for Medicines and Medical Devices notifies the Pharmacovigilance Risk Assessment Committee on the issues concerned and provisions of Article 819^{10} (2) shall apply. The Pharmacovigilance Risk Assessment Committee shall issue a recommendation according to the procedure laid down in Article 32 of Directive 2001/83/EC. 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 Article 819^{11} shall apply. Where urgent action is considered necessary, the procedure shall apply as laid down in Articles 819^{9}-819^{11}. The National Agency for Medicines and Medical Devices, the competent authority of any other Member State concerned or the European Commission shall clearly identify the question which is referred to the Committee for Medicinal products for Human Use for consideration and duly inform the applicant or marketing authorisation holder.

(3) The National Agency for Medicines and Medical Devices and the applicant or the marketing authorisation holder shall supply the Committee with all available information relating to the matter in question

(4) Where the referral to the Pharmacovigilance Risk Assessment Committee concerns a range of medicinal products or a therapeutic class, the procedure may be limited to certain specific parts of the authorisation; in that event, Article 743 shall apply only if they were covered by the authorisation procedures referred to in this section."

50. **Article 744 is deleted.**

51. **Article 769 (1)(e) is amended as follows:**

"e) a description of the adverse reactions which may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case; for medicinal products included in the list referred to in Article 23 of Regulation (EC) No 726/2004, the following additional statement shall be included "This medicinal product is subject to additional monitoring"; this statement shall be preceded by the black symbol referred to in Article 23 of Regulation (EC) No. 726/2004 and followed by an appropriate standardised explanatory sentence; For all medicinal products, a standardised text shall be included, expressly asking patients to communicate any suspected adverse reaction to his/her doctor, pharmacist, healthcare professional or, according to Article 819^{1} (1), directly to the National Agency for Medicines and Medical Devices, specifying the different ways of reporting available (electronic reporting, postal address and/or others) in compliance with Article 819^{1}(1)."

52. Article 773, (3) is amended as follows:

"(3) When the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the National Agency for Medicines and Medical Devices may, subject to measures they consider necessary to safeguard human health, grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet; the National Agency for

Medicines and Medical Devices may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in Romanian.”

53. The title of a new section is inserted after “Chapter X – Pharmacovigilance”, reading:

"SECTION 1
General provisions"

54. Article 812 is amended as follows:

"Art. 812. - (1) The National Agency for Medicines and Medical Devices shall organise and operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in European Union pharmacovigilance activities. The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards as regards the health of patients or the public. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure.

(2) By means of this pharmacovigilance system, the National Agency for Medicines and Medical Devices evaluates all information scientifically, considers options for risk minimisation and prevention and takes regulatory action concerning the marketing authorisation as necessary. The National Agency for Medicines and Medical Devices performs a regular audit of its pharmacovigilance system and reports the results to the Commission on 21 September 2013 at the latest and then every 2 years thereafter.

(3) Coordination and conduct of work of the Pharmacovigilance system is performed through the specialised unit of the National Agency for Medicines and Medical Devices.

(4) Under the coordination of the European Medicines Agency, the National Agency for Medicines and Medical Devices takes part in international harmonisation and standardisation of technical measures in relation to pharmacovigilance.” The National Agency for Medicines and Medical Devices shall organise and operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in European Union pharmacovigilance activities. The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards as regards the health of patients or the public. That information shall in particular refer to adverse reactions in humans, due to the use of the product according to the specifications of the marketing authorisation and to those associated with professional exposure.

55. **Article 813 is amended as follows:**

"Art. 813. - (1) The National Agency for Medicines and Medical Devices has the following duties:

a) to take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the specialised unit as per Article 812 (3); for performance of these tasks, organisations representing consumers, patients and healthcare professionals may be involved as appropriate;

b) to facilitate patient reporting through the provision of alternative reporting formats, other than the web-based formats available to healthcare professionals on the website of the National Agency for Medicines and Medical Devices;

c) to take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;

d) to ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-portal and through other means of publicly available information as necessary;

e) to ensure, through the methods for collecting information and where necessary through the follow-up of suspected adverse reaction reports, that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in Romania which is the subject of a suspected adverse reaction report, with due regard to the name of the medicinal product, in accordance with Article 695 (20) and the batch number;

f) to take the necessary measures to ensure that a marketing authorisation holder who fails to discharge the obligations laid down in this chapter, is subject to effective, proportionate and dissuasive penalties.

(2) For the purposes of point (1), a) and e), the Ministry of Health may impose specific obligations on doctors, pharmacists and other health-care professionals."

56. Article 814 is amended as follows:

"Art. 814 - The National Agency for Medicines and Medical Devices may represent or delegate any of the tasks entrusted to it under this chapter, to another Member State subject to a written agreement of the latter. The National Agency for Medicines and Medical Devices may represent no more than one other Member State. Where The National Agency for Medicines and Medical Devices is the delegating Member State, it shall inform the European Commission, the European Medicines Agency and all other Member States of the delegation in writing and makes that information public."

57. Article 815 is amended as follows:

"Art. 815. - (1) The marketing authorisation holder shall operate a pharmacovigilance system for the fulfilment of his pharmacovigilance tasks equivalent to the pharmacovigilance system of the National Agency for Medicines and Medical Devices, pursuant to Article 812 (1).

(2) By means of the pharmacovigilance system referred to in paragraph (1), the marketing authorisation holder shall evaluate all information scientifically, consider options for risk minimisation and prevention and take appropriate measures as necessary. The marketing authorisation holder shall perform a regular audit of his pharmacovigilance system. He shall place a note concerning the main findings of the audit on the pharmacovigilance system master file and, based on the audit findings, ensure that an appropriate corrective action plan is prepared and implemented. Once the corrective actions have been fully implemented, the note may be removed.

(3) As part of the pharmacovigilance system, the marketing authorisation holder shall:

a) have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance;

b) maintain and make available on request a pharmacovigilance system master file;

c) operate a risk management system for each medicinal product;

d) monitor the outcome of risk minimisation measures which are contained in the risk management plan or which are laid down as conditions of the marketing authorisation pursuant to Articles 726^{1}, 727 or 727^{1};

e) update the risk management system and monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.

(4) The qualified person referred to under (3), a) shall reside and operate in the European Union and shall be responsible for the establishment and maintenance of the pharmacovigilance system. The marketing authorisation holder shall submit the name and contact details of the qualified person to the National Agency for Medicines and Medical Devices and the European Medicines Agency.

(5) Notwithstanding the provisions of paragraph (4), the National Agency for Medicines and Medical Devices may request the nomination of a contact person for pharmacovigilance issues at national level reporting to the qualified person responsible for pharmacovigilance activities."

58. Article 816 is amended as follows:

"Art. 816. - (1) Without prejudice to paragraphs (2), (3) and (4) of this Article, holders of marketing authorisations granted before entrance into force of this law shall, by way of derogation from Article 815 (3), c), not be required to operate a risk management system for each medicinal product.

(2) The National Agency for Medicines and Medical Devices may impose an obligation on a marketing authorisation holder to operate a risk management system, as referred to in Article 815 (3), c) if there are concerns about the risks affecting the risk-benefit balance of an authorised medicinal product. In that context, the National Agency for Medicines and Medical Devices authority shall also oblige the marketing authorisation holder to submit a detailed description of the risk- management system which he intends to introduce for the medicinal product concerned. The imposition of such obligations shall be duly justified, notified in writing and shall include the timeframe for submission of the detailed description of the risk management system.

(3) If the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation, the National Agency for Medicines and Medical Devices, shall provide the marketing authorisation holder with an opportunity to present written observations in response to the imposition of the obligation within a time limit specified by the authority.

(4) On the basis of the written observations submitted by the marketing authorisation holder, the National Agency for Medicines and Medical Devices shall withdraw or confirm the obligation in question. Where The National Agency for Medicines and Medical Devices confirms the obligation, the marketing authorisation shall be varied accordingly to include the measures to be taken as part of the risk management system as conditions of the marketing authorisation referred to in Article 726^{1} (1), a)."

59. Article 817 is amended as follows:

"Art. 817. - (1) The National Agency for Medicines and Medical Devices from charging fees to marketing authorisation holders for performing activities connected with Pharmacovigilance, pursuant to Article 857.

(2) The funds from such activities are fully used by the National Agency for Medicines and Medical Devices for the sole purpose of funding pharmacovigilance activities, operation of communication networks and market surveillance.

(3) To that purpose, under the law, the Ministry of Health as chief credit accountant sets up as self-funded activity all pharmacovigilance-related services provided by the National Agency for Medicines and Medical Devices."

60. The title of a new section, section 2, is inserted after Article 817, as follows:

"SECTION 2
Transparency and communication"

61. **Article 818 is amended as follows:**

"Art. 818. - The National Agency for Medicines and Medical Devices sets up and maintains a national medicines web-portal electronically linked to the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004. By means of the national medicines web-portals, the National Agency for Medicines and Medical Devices makes publicly available at least the following:

a) public assessment reports, together with a summary thereof;

b) summaries of product characteristics and package leaflets;

c) summaries of risk management plans for medicinal products authorised in accordance with this Directive;

d) the list of medicinal products referred to in Article 23 of Regulation (EC) No 726/2004;

e) information on the different ways of reporting suspected adverse reactions to medicinal products to The National Agency for Medicines and Medical Devices by healthcare professionals and patients, including the web-based structured forms referred to in Article 25 of Regulation (EC) No 726/2004."

62. A new article, Article 818[1], is inserted after Article 818, reading:

"Art. 818[1]. - (1) As soon as the marketing authorisation holder 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, he shall be required to inform the national competent authorities, the European Medicines Agency and the European Commission. The marketing authorisation holder shall ensure that information to the public is presented objectively and is not misleading.

(2) Unless urgent public announcements are required for the protection of public health, the National Agency for Medicines and Medical Devices, the European Medicines Agency and the European Commission shall inform each other not less than 24 hours prior to a public announcement relating to information on pharmacovigilance concerns.

(3) Under the coordination of the European Medicines Agency, the National Agency for Medicines and Medical Devices shall make all reasonable efforts to agree on a common message in relation to the safety of the medicinal product concerned and the timetables for their distribution. The Pharmacovigilance Risk Assessment Committee shall, at the request of the European Medicines Agency, provide advice on those safety announcements.

(4) When The National Agency for Medicines and Medical Devices make public information referred to in paragraphs (2) and (3), information of a personal or commercially confidential nature shall be deleted unless its public disclosure is necessary for the protection of public health"

63. The title of a new section, section 3, is inserted after Article 818[1], as follows:

"SECTION 3
Recording, reporting and assessment of pharmacovigilance data"

64. A new paragraph, paragraph 1, is inserted after the title of Section 3, reading:

"PARAGRAPH 1
Recording and reporting of suspected adverse reactions"

65. Article 819 is amended as follows:

"Art. 819. - (1) Marketing authorisation holders shall record all suspected adverse reactions in the Union or in third countries which are brought to their attention, whether reported spontaneously by patients or healthcare professionals, or occurring in the context of a post-authorisation study. Marketing authorisation holders shall ensure that those reports are accessible at a single point within the Union. By way of derogation from the first subparagraph, suspected adverse reactions occurring in the context of a clinical trial shall be recorded and reported in accordance with Norms relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, approved through order of the minister of health.

(2) Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients and healthcare professionals.

(3) Marketing authorisation shall submit electronically to the database and data-processing network referred to in Article 24 of Regulation (EC) No 726/2004 (hereinafter referred to as the "EudraVigilance database") information on all serious suspected adverse reactions that occur in the Union and in third countries within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event. Marketing authorisation holders shall submit electronically to the Eudravigilance database information on all non-serious suspected adverse reactions that occur in the Union, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event. For medicinal products containing the active substances referred to in the list of publications monitored by the European Medicines Agency pursuant to Article 27 of Regulation (EC) 726/2004, marketing authorisation holders shall not be required to report to the Eudravigilance database the suspected adverse reactions recorded in the listed medical literature, but they shall monitor all other medical literature and report any suspected adverse reactions.

(4) Marketing authorisation holders shall establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports. They shall also collect follow-up information on these reports and submit the updates to the Eudravigilance database.

(5) Marketing authorisation holders shall collaborate with the European Medicines Agency, the National Agency for Medicines and Medical Devices and the national competent authorities in the detection of duplicates of suspected adverse reaction reports."

66. Seventeen new articles, Articles 819[1]-819[17], are inserted after Article 819, reading as follows:

"Art. 819[1]. - (1) The National Agency for Medicines and Medical Devices shall record all suspected adverse reactions that occur in Romania which are brought to its attention from healthcare professionals and patients and ensure that reports of such reactions may be submitted by means of the national medicines web-portal or by other means; if appropriate, the National Agency for Medicines and Medical Devices involves patients and healthcare professionals in the follow-up of any reports they receive in order to comply with Article 813 (1), c) and e).

(2) For reports submitted by a marketing authorisation holder concerning adverse reactions occurring in Romania, the National Agency for Medicines and Medical Devices involve the marketing authorisation holder in the follow-up of the reports.

(3) The National Agency for Medicines and Medical Devices collaborates with the European Medicines Agency and the marketing authorisation holders in the detection of duplicates of suspected adverse reaction reports.

(4) Within 15 days following the receipt of the reports of serious suspected adverse reactions referred to in paragraph (1), the National Agency for Medicines and Medical Devices submits the serious suspected adverse reactions reports electronically to the EudraVigilance database. Within 90 days from the receipt of reports referred to in paragraph (1), the National Agency for Medicines and Medical Devices submits reports of non-serious suspected adverse reactions electronically to the EudraVigilance database. Marketing authorisation holders access those reports through the EudraVigilance database.

(5) The National Agency for Medicines and Medical Devices ensures that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the EudraVigilance database and to any authorities, bodies, organisations and/or institutions, responsible for patient safety within Romania. The latter ensure in their turn that the National Agency for Medicines and Medical Devices is informed of any suspected adverse reactions brought to the attention of any other authority within Romania. These reports shall be appropriately identified in the forms referred to in Article 25 of Regulation (EC) No 726/2004.

(6) Unless there are justifiable grounds resulting from pharmacovigilance activities, the National Agency for Medicines and Medical Devices shall not individually impose any additional obligations on marketing authorisation holders for the reporting of suspected adverse reactions."

67. A new paragraph, (2), is inserted after Article 819[1], as follows:

"PARAGRAPH 2
Periodic safety update reports

Art. 819[2]. - (1) Marketing authorisation holders submit to the European Medicines Agency periodic safety update reports containing:

a) summaries of data relevant to the benefits and risks of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorisation;

b) a scientific evaluation of the risk-benefit balance of the medicinal product;

c) all data relating to the volume of sales of the medicinal product and any data in possession of the marketing authorisation holder relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product.

The evaluation referred to in point (b) shall be based on all available data, including data from clinical trials in unauthorised indications and populations. The periodic safety update reports shall be submitted electronically.

(2) By means of the repository referred to in Article 25a of Regulation (EC) No 726/2004, the National Agency for Medicines and Medical Devices, the members of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the Coordination group may access the reports referred to in (1), as made available by the European Medicines Agency.

(3) By way of derogation from paragraph (1) of this Article, holders of Marketing authorisation for medicinal products referred to in Article 704 (1) or Article 705 and holders of Marketing authorisations granted based on simplified procedures for medicinal products referred to in Articles 711 or 714 shall submit periodic safety update reports for such medicinal products in the following cases:

a) where such obligation has been laid down as a condition in the marketing authorisation in accordance with Article 726[1] or Article 727; or

b) when requested by the National Agency for Medicines and Medical Devices or other competent authority, where concerns arise relating to pharmacovigilance data or due to the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted. The assessment reports of the requested periodic safety update reports shall be communicated to the Pharmacovigilance Risk Assessment Committee, which shall consider whether there is a need for a single assessment report for all marketing authorisations for medicinal products containing the same active substance and inform the Coordination group or the Committee for Medicinal Products for Human Use accordingly, in order to apply the procedures laid down in Article 819[3] (4) and Article 819[5].

Art. 819[3]. - (1) The frequency with which the periodic safety update reports are to be submitted shall be specified in the marketing authorisation. The dates of submission according to the specified frequency shall be calculated from the date of the authorisation.

(2) A regards marketing authorisations which were granted before entry into force of this bill, and for which the frequency and dates of submission of the periodic safety update reports are not laid down as a condition to the marketing authorisation, shall submit the periodic safety update reports in accordance with the second subparagraph of this paragraph until another frequency or other dates of submission of the reports are laid down in the marketing

authorisation or determined in accordance with paragraphs (4), (5) or (6). Periodic safety update reports shall be submitted to the National Agency for Medicines and Medical Devices immediately upon request or in accordance with the following:

a) where a medicinal product has not yet been placed on the market, at least every 6 months following authorisation and until the placing on the market;

b) where a medicinal product has been placed on the market, at least every 6 months during the first 2 years following the initial placing on the market, once a year for the following 2 years and at three-yearly intervals thereafter.

(3) Paragraph (2) shall also apply to medicinal products which are authorised only in one Member State and for which paragraph (4) does not apply.

(4) Where medicinal products that are subject to different marketing authorisations contain the same active substance or the same combination of active substances, the frequency and dates of submission of the periodic safety update reports resulting from the application of paragraphs (1) and (2) may be amended and harmonised to enable a single assessment to be made in the context of a periodic safety update report work-sharing procedure and to set a Union reference date from which the submission dates are calculated. This harmonised frequency for the submission of the reports and the Union reference date may be determined, after consultation of the Pharmacovigilance Risk Assessment Committee, by one of the following:

a) the Committee for Medicinal Products for Human Use, where at least one of the marketing authorisations for the medicinal products containing the active substance concerned has been granted in accordance with the centralised procedure provided for in Chapter 1 of Title II of Regulation (EC) No 726/2004;

b) the Coordination group, in other cases than those referred to under a).

Marketing authorisation holders submit reports according to the harmonised frequency determined pursuant to the first and second subparagraphs and made public by the European Medicines Agency; Marketing authorisation holders submit an application for a variation of the marketing authorisation accordingly.

(5) For the purposes of paragraph (4), the Union reference date for medicinal products containing the same active substance or the same combination of active substances shall be one of the following:

a) the date of the first marketing authorisation in the Union of a medicinal product containing that active substance or that combination active substances;

b) if the date referred to in a) cannot be ascertained, the earliest of the known dates of the marketing authorisations for a medicinal product containing that active substance or that combination of active substances.

(6) Marketing authorisation holders are allowed to submit requests to the Committee for Medicinal Products for Human Use or the Coordination group, as appropriate, to determine Union reference dates or to change the frequency of submission periodic safety update reports on one of the following grounds:

a) for issues related to public health;

b) in order to avoid a duplication of the assessment;

c) in order to obtain international harmonisation.

Such requests shall be submitted in writing and shall be duly justified; following the consultation with the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use or the Coordination group may either approve or deny such requests; marketing authorisation holders apply any change in the dates or the frequency of submission of periodic safety update reports as made public by the European Medicines Agency and accordingly submit an application for a variation of the marketing authorisation.

(7) By means of the European medicines web-portal, the European Medicines Agency makes public a list of European Union reference dates and frequency of submission of periodic

safety update reports; any change to the dates of submission and frequency of periodic safety update reports specified in the marketing authorisation as a result of the application of (4), (5) and (6), takes effect 6 months after the date of such publication.

Art. 819[4]. - The National Agency for Medicines and Medical Devices assesses periodic safety update reports to determine whether there are new risks or whether risks have changed or whether there are changes to the risk-benefit balance of medicinal products.

Art. 819[5]. - (1) A single assessment of periodic safety update reports shall be performed for medicinal products authorised in more than one Member State and, in the cases falling under Article 819[3] (4)-(6), for all medicinal products containing the same active substance or the same combination of active substances and for which a Union reference date and frequency of periodic safety update reports has been established. The single assessment is performed:

a) either by a Member State appointed by the Coordination group where none of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Chapter 1 of Title II of Regulation (EC) No 726/2004; or

b) a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee, where at least one of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Chapter 1 of Title II of Regulation (EC) 726/2004.

When selecting the Member State in accordance with a), the Coordination group shall take into account whether any Member State is acting as a reference Member State, in accordance with Article 736 (1).

(2) Where the National Agency for Medicines and Medical Devices is assigned to perform the single assessment, it shall prepare an assessment report within 60 days of receipt of the periodic safety update report and send it to the European Medicines Agency and to the Member States concerned. The European Medicines Agency shall send the report to the marketing authorisation holder. Within 30 days of receipt of the assessment report, the Member States and the marketing authorisation holder may submit comments to the European Medicines Agency and to the National Agency for Medicines and Medical Devices.

(3) Following the receipt of the comments referred to under (2), the National Agency for Medicines and Medical Devices shall within 15 days update the assessment report taking into account any comments submitted, and forward it to the Pharmacovigilance Risk Assessment Committee. The Pharmacovigilance Risk Assessment Committee shall adopt the assessment report with or without further changes at its next meeting and issue a recommendation. The recommendation shall mention the divergent positions with the grounds on which they are based. The European Medicines Agency shall include the adopted assessment report and the recommendation in the repository set up under Article 25a of Regulation (EC) No 726/2004 and forward both to the marketing authorisation holder.

Art. 819[6]. - Following the assessment of periodic safety update reports, the National Agency for Medicines and Medical Devices considers whether any action concerning the marketing authorisation for the medicinal product concerned is necessary. The National Agency for Medicines and Medical Devices may decide to maintain, vary, suspend or revoke the marketing authorisation as appropriate.

Art. 819[7]. - (1) In the case of a single assessment of periodic safety update reports that recommends any action concerning more than one marketing authorisation in accordance with Article 819[5] (1), which does not include any marketing authorisation granted in accordance with the centralised procedure provided for in Chapter 1 of Title II of Regulation (EC) 726/2004, the Coordination group shall, within 30 days of receipt of the report of the Pharmacovigilance Risk Assessment Committee, consider the report and reach a position on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable for the implementation of the agreed position.

(2) If, within the Coordination group, the Member States represented reach agreement on the action to be taken by consensus, the chairman shall record the agreement and send it to the marketing authorisation holder and the Member States. The National Agency for Medicines and Medical Devices and competent authorities in the other Member States adopt necessary measures to maintain, vary, suspend or revoke the marketing authorisations concerned in accordance with the timetable for implementation determined in the agreement. In the event of a variation, the marketing authorisation holder shall submit to the National Agency for Medicines and Medical Devices an appropriate application for a modification, including an updated summary of product characteristics and package leaflet within the determined timetable for implementation. If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the Coordination group shall be forwarded to the European Commission which shall apply the procedure laid down in Articles 33 and 34 of Directive 2001/83/EC. Where the agreement reached by the Member States represented within the Coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Coordination group shall attach to the agreement or the majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.

(3) In the case of a single assessment of periodic safety update reports that recommends any action concerning more than one marketing authorisation in accordance with Article 819^5 (1), which includes at least one marketing authorisation granted in accordance with the centralised procedure provided for in Chapter 1 of Title II of Regulation (EC) No. 726/2004, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the report of the Pharmacovigilance Risk Assessment Committee, consider the report and adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable for the implementation of the opinion. Where this opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.

(4) On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in (3):

a) the European Commission shall adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations granted by the Member States and concerned by the procedure provided for in this paragraph; and

b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, the European Commission shall adopt a decision to vary, suspend or revoke the marketing authorisations granted in accordance with the centralised procedure provided for in Regulation (EC) No 726/2004 and concerned by the procedure provided for in this paragraph. Provisions of Articles 33 and 34 of Directive 2001/83/EC apply to the adoption of the decision referred to under a), as well as to its implementation by the National Agency for Medicines and Medical Devices. Provisions of Article 10 of Regulation (EC) No 726/2004 shall apply to the decision referred to under b). Where the Commission adopts such decision, it may also adopt a decision addressed to the National Agency for Medicines and Medical Devices competent authorities in the other Member States pursuant to Article 127a of Directive 2001/83/EC. The National Agency for Medicines and Medical Devices implements the decision of the European Commission as under a) and b), in line with provisions of Articles 741-742 and Article 847, respectively."

68. A new paragraph, paragraph 3, is inserted after Article 819^7, as follows:

"PARAGRAPH 3

Signal detection

Art. 819[8]. - (1) Regarding medicinal products authorised in accordance with this title, the National Agency for Medicines and Medical Devices in collaboration with the European Medicines Agency, shall take the following measures:

a) monitor the outcome of risk minimisation measures contained in risk management plans and of the conditions referred to in Articles 726[1], 727 or 727[1];

b) assess updates to the risk management system;

c) monitor the data in the EudraVigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the risk-benefit balance.

(2) The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or changes to the risk-benefit balance. Where it considers that follow-up action may be necessary, the assessment of those signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue.

(3) The European Medicines Agency and the National Agency for Medicines and Medical Devices, and the marketing authorisation holder shall inform each other in the event of new risks or risks that have changed or changes to the risk-benefit balance being detected. The National Agency for Medicines and Medical Devices ensures that marketing authorisation holders inform the Agency and national competent authorities in the event of new risks or risks that have changed or when changes to the risk-benefit balance have been detected."

69. A new paragraph, paragraph 4, is inserted after Article 819[8], reading as follows:

"PARAGRAPH 4
Urgent European Union procedure"

Art. 819[9]. - (1) The National Agency for Medicines and Medical Devices, the competent authority in another Member State or, where the case, the European Commission, may initiate the procedure provided for in this paragraph, by informing the other EU competent authorities, the European Medicines Agency and the European Commission when urgent action is considered necessary, as a result of the evaluation of data resulting from pharmacovigilance activities, in any of the following cases:

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;

d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, he has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or that he intends to do so;

e) it considers that a new contraindication, a reduction in the recommended dose, or a restriction to the indications is necessary.

The European Medicines Agency verifies whether the safety concern relates to medicinal products other than the one covered by the information, or whether it is common to all products belonging to the same range or therapeutic class. Where the medicinal product(s) involved is /are authorised in more than one Member State, the European Medicines Agency without undue delay informs the initiator of the procedure of the outcome of this verification, and the procedures laid down in Articles 819[10] and 819[11]. Otherwise, the safety concern shall be addressed by the Member State concerned. The European Medicines Agency or the Member

State, as applicable, shall make information that the procedure has been initiated available to marketing authorisation holders.

(2) Without prejudice to the provisions of paragraph (1) of this Article 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 in Romania until a definitive decision is adopted. The National Agency for Medicines and Medical Devices informs The European Commission, the European Medicines Agency and competent authorities in the other Member States no later than the following working day of the reasons for its action.

(3) 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 paragraph 1, 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.

(4) 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 found that a 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, the European Medicines Agency may 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.

(5) At the time of the information referred to in (1), the National Agency for Medicines and Medical Devices makes available to the European Medicines Agency all relevant scientific information that it has at its disposal and any assessment performed.

Art. 819^{10}. - (1) Following receipt of the information referred to in Article 819^{9} (1), the European Medicines Agency publicly announces the initiation of the procedure by means of the European medicines web-portal. In parallel, the National Agency for Medicines and Medical Devices and the other Member States may publicly announce the initiation on their national medicines web-portals. The announcement shall specify the matter submitted to the European Medicines Agency in accordance with Article 819^{9}, and the medicinal products and, where applicable, the active substances concerned. The announcement shall 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 may be submitted.

(2) The Pharmacovigilance Risk Assessment Committee shall assess the matter which has been submitted to the European Medicines Agency in accordance with Article 819^{9}. The rapporteur shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use and the Reference Member State for the medicinal products concerned. For the purposes of that assessment, the marketing authorisation holder may submit comments in writing. Where the urgency of the matter permits, the Pharmacovigilance Risk Assessment Committee may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern. The hearings shall be held in accordance with the modalities specified by the European Medicines Agency and shall be announced by means of the European medicines web-portal. The announcement shall specify the modalities of participation in the public hearing, due regard shall be given to the therapeutic effect of the medicinal product. Where a marketing authorisation holder or another person intending to submit information has confidential data

relevant to the subject of the procedure, he may request permission to present that data to the Pharmacovigilance Risk Assessment Committee in a non- public hearing.

(3) Within 60 days of the information being submitted, the Pharmacovigilance Risk Assessment Committee shall make a recommendation, stating the reasons on which it is based, having due regard to the therapeutic effect of the medicinal product. The recommendation shall mention the divergent positions and the grounds on which they are based. In the case of urgency, and on the basis of a proposal by its chairman, the Pharmacovigilance Risk Assessment Committee may agree to a shorter deadline. The recommendation shall include any or a combination of the following conclusions:

a) no further evaluation or action is required at European Union level;

b) the marketing authorisation holder should conduct further evaluation of data together with the follow-up of the results of that evaluation;

c) the marketing authorisation holder should sponsor a post-authorisation safety study together with the follow up evaluation of the results of that study;

d) the Member States or marketing authorisation holder should implement risk minimisation measures;

e) the marketing authorisation should be suspended, revoked or not renewed;

f) the marketing authorisation should be varied.

For the purposes of point d), the recommendation shall specify the risk minimisation measures recommended and any conditions or restrictions to which the marketing authorisation should be made subject. Where, in the cases referred to in point f), it is recommended to change or add information in the summary of product characteristics or the labelling or package leaflet, the recommendation shall suggest the wording of such changed or added information and where in the summary of the product characteristics, labelling or package leaflet such wording should be placed.

Art. 819^{11}. - (1) Where the scope of the procedure, as determined in accordance with Article 819^{9} (4), does not include any marketing authorisation granted in accordance with the centralised procedure provided for in Chapter 1 of Title II of Regulation (EC) 726/2004, the Coordination group shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and reach a position on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisation concerned, including a timetable for the implementation of the agreed position. Where an urgent adoption of the position is necessary, and on the basis of a proposal by its chairman, the Coordination group may agree to a shorter deadline.

(2) If, within the Coordination group, the Member States represented reach agreement on the action to be taken by consensus, the chairman shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend, revoke or refuse renewal of the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement. In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the National Agency for Medicines and Medical Devices an appropriate application for a variation, including an updated summary of product characteristics and package leaflet within the determined timetable for implementation.

If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the Coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Articles 33 and 34 of Directive 2001/83/EC. However, by way of derogation from Article 34 (1) of Directive 2001/83/EC, the procedure shall apply as referred to in Article 121 (2) of Directive 2001/83/EC. In that case, the National Agency for Medicines and Medical Devices applies decisions of the European Commission.

Where the agreement reached by the Member States represented within the Coordination group or the position of the majority of the Member States represented within the Coordination group differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.

(3) Where the scope of the procedure, as determined in accordance with Article 819^{9} (4), includes at least one marketing authorisation granted in accordance with the centralised procedure provided for in Chapter 1 of Title II of Regulation (EC) 726/2004, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and adopt an opinion on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisations concerned. Where an urgent adoption of the opinion is necessary, and on the basis of a proposal by its chairman, the Committee for Medicinal Products for Human Use may agree to a shorter deadline. Where the opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.

(4) On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in (3):

a) The European Commission may adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations that are granted by the Member States and that are subject to the procedure provided for in this paragraph; and

b) where the opinion is that regulatory action is necessary, the European Commission may adopt a decision to vary, suspend, revoke or refuse renewal of the marketing authorisations granted in accordance with Regulation (EC) No 726/2004 and subject to the procedure provided for in this paragraph.

Articles 33 and 34 of Directive 2001/83/EC shall apply to the adoption of the decision referred to in point (a) as well to its implementation by the National Agency for Medicines and Medical Devices. By way of derogation from Article 34 (1) of Directive 2001/83/EC, the procedure referred to in Article 121(2) of Directive 2001/83 shall apply. Provisions of Article 10 of Regulation (EC) 726/2004 apply to the decision referred to in point b). By way of derogation from Article 10 (2) 10 of Regulation (EC) 726/2004, the procedure referred to in Article 87 (2) shall apply. Where the Commission adopts such decision, it may also adopt a decision addressed to the Member States pursuant to Article 127a of Directive 2001/83/EC. The National Agency for Medicines and Medical Devices applies decisions of the European Commission as mentioned under a) and b), pursuant to Articles 741-742 and Article 847 of this Title, respectively."

68. A new paragraph, paragraph 5, is inserted after Article 819^{11}, as follows:

"PARAGRAPH 5

Publication of assessments

Art. 819^{12}. - The final assessment conclusions, recommendations, opinions and decisions referred to in Articles 819^{2}-819^{11} are made public by means of the European medicines web-portal under the management of the European Medicines Agency."

71. A new section, section 4, is inserted under Title XVII, Chapter X, after Article 819^{12}, as follows:

"SECTION 4
Supervision of post-authorisation safety studies"

Art. 819^{13}. - (1) This section applies to non-interventional post-authorisation safety studies which are initiated, managed or financed by the marketing authorisation holder voluntarily or pursuant to obligations imposed in accordance with Articles 726^{1} or 727^{1} and which involve the collection of safety data from patients or healthcare professionals.

(2) This section is without prejudice to national and Union requirements for ensuring the well-being and rights of participants in non-interventional post-authorisation safety studies.

(3) The studies shall not be performed where the act of conducting the study promotes the use of a medicinal product.

(4) Payments to healthcare professionals for participating in non-interventional post-authorisation safety studies shall be restricted to the compensation for time and expenses incurred.

(5) The National Agency for Medicines and Medical Devices may require the marketing authorisation holder to submit the protocol and the progress reports to the competent authorities of the Member States in which the study is conducted.

(6) The marketing authorisation holder sends the final report to the competent authorities of the Member States in which the study was conducted within 12 months of the end of data collection.

(7) While a study is being conducted, the marketing authorisation holder shall monitor the data generated and consider its implications for the risk-benefit balance of the medicinal product concerned. Any new information which might influence the evaluation of the risk-benefit balance of the medicinal product shall be communicated to the competent authorities of the Member State in which the medicinal product has been authorised in accordance with Article 728. The obligation laid down in the second subparagraph is without prejudice to the information on the results of studies that the marketing authorisation holder shall make available by means of the periodic safety update reports as laid down in Article 819^{2}.

(8) Articles 819^{14}- 819^{17} apply exclusively to studies referred to in (1), which are conducted pursuant to an obligation imposed in accordance with Articles 726^{1} or 727^{1}.

Art. 819^{14}. - (1) Before a study is conducted, the marketing authorisation holder shall submit a draft protocol to the Pharmacovigilance Risk Assessment Committee, except for studies to be conducted in only one Member State that requests the study according to Article 727^{1}. For such studies, the marketing authorisation holder shall submit a draft protocol to the National Agency for Medicines and Medical Devices.

(2) Within 60 days of the submission of the draft protocol, the National Agency for Medicines and Medical Devices or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall issue the following:

a) a letter endorsing the draft protocol;

b) a letter of objection, which shall set out in detail the grounds for the objection, in any of the following cases:

(i) it considers that the conduct of the study promotes the use of a medicinal product;

(ii) it considers that the design of the study does not fulfil the study objectives; or

c) a letter notifying the marketing authorisation holder that the study is a clinical trial falling under the scope of Norms relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, approved through order of the minister of health.

(3) The study may commence only when the written endorsement from the National Agency for Medicines and Medical or the Pharmacovigilance Risk Assessment Committee, as appropriate, has been issued; where a letter of endorsement as referred to in paragraph (2) a),

the marketing authorisation holder shall forward the protocol to the National Agency for Medicines and Medical Devices, and may thereafter commence the study according to the endorsed protocol.

Art. 819[15]. - After a study has been commenced, any substantial amendments to the protocol shall be submitted, before their implementation, to the National Agency for Medicines and Medical Devices or to the Pharmacovigilance Risk Assessment Committee, as appropriate. The National Agency for Medicines and Medical Devices or The Pharmacovigilance Risk Assessment Committee, as appropriate, assesses the amendments and informs the marketing authorisation holder of its endorsement or objection. Where applicable, the marketing authorisation holder shall inform Member States in which the study is conducted.

Art. 819[16]. - (1) Upon completion of the study, a final study report shall be submitted to the National Agency for Medicines and Medical Devices or to the The Pharmacovigilance Risk Assessment Committee within 12 months of the end of data collection unless a written waiver has been granted by the The National Agency for Medicines and Medical Devices or The Pharmacovigilance Risk Assessment Committee, as appropriate.

(2) The marketing authorisation holder shall evaluate whether the results of the study have an impact on the marketing authorisation and shall, if necessary, submit to the national competent authorities an application to vary the marketing authorisation.

(3) Together with the final study report, the marketing authorisation holder shall electronically submit an abstract of the study results to the National Agency for Medicines and Medical Devices or The Pharmacovigilance Risk Assessment Committee.

Art. 819[17]. - (1) Based on the results of the study and after consultation of the marketing authorisation holder, the Pharmacovigilance Risk Assessment Committee may make recommendations concerning the marketing authorisation, stating the reasons on which they are based. The recommendations shall mention the divergent positions and the grounds on which they are based.

(2) When recommendations for the variation, suspension or revocation of the marketing authorisation are made for a medicinal product authorised by the Member States pursuant to Directive 2001/83/EC, the National Agency for Medicines and Medical Devices and competent authorities in the other Member States represented within the Coordination group shall agree a position on the matter taking into account the recommendation referred to in (1) and including a timetable for the implementation of the agreed position. If, within the Coordination group, the Member States represented reach agreement on the action to be taken by consensus, the chairman shall record the agreement and send it to the marketing authorisation holder and the Member States. The National Agency for Medicines and Medical Devices and competent authorities in the other Member States adopt necessary measures to maintain, vary, suspend or revoke the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement. In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the National Agency for Medicines and Medical Devices an appropriate application for a variation, including an updated summary of product characteristics and package leaflet within the determined timetable for enforcement. The agreement shall be made public on the European medicines web-portal established in accordance with Article 26 of Regulation (EC) 726/2004. If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the Coordination group shall be forwarded to the Commission, which shall apply the procedure laid down in Articles 33 and 34 of Directive 2001/83. In that case, pursuant to Articles 741-742 of this Title, the National Agency for Medicines and Medical Devices applies decisions of the European Commission. Where the agreement reached by the Member States represented within the Coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Coordination

group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation."

72. A new section, section 5, is inserted under Title XVII, Chapter X, after Article 819[17] as follows:

"SECTION 5
Implementation, delegation and guidance"

73. **Article 820 is amended as follows:**

"Art. 820. - In order to harmonise the performance of the pharmacovigilance activities provided for in this law, the National Agency for Medicines and Medical Devices applies implementing measures as adopted by the European Commission in the following areas for which pharmacovigilance activities are provided for in Article 702 (4) and in Articles 812, 815, 816, 819, 819[1], 819[2], 819[8], 819[14] and 819[16]:

a) the content and maintenance of the pharmacovigilance system master file kept by the marketing authorisation holder;

b) the minimum requirements for the quality system for the performance of pharmacovigilance activities by the national competent authorities and the marketing authorisation holder;

c) the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;

d) the minimum requirements for the monitoring of data in the EudraVigilance database to determine whether there are new risks or whether risks have changed;

e) the format and content of the electronic transmission of suspected adverse reactions by Member States and the marketing authorisation holder;

f) the format and content of electronic periodic safety update reports and risk management plans;

g) the format of protocols, abstracts and final study reports for the post-authorisation safety studies.

The implementing measures take account of the work on international harmonisation carried out in the area of pharmacovigilance and shall, where necessary, be revised to take account of technical and scientific progress. The National Agency for Medicines and Medical Devices applies any changes deemed necessary to update this chapter to take account of technical and scientific progress after adoption by the European Commission."

74. A new article, Article 820[1], is inserted after Article 820, as follows:

"Art. 820[1]. - In order to facilitate the performance of pharmacovigilance activities within the Union, the National Agency for Medicines and Medical Devices works together with the European Medicines Agency and other interested parties to draw up the following:

a) guidance on good pharmacovigilance practices for both competent authorities and marketing authorisation holders;

b) scientific guidance on post-authorisation efficacy studies."

75. Under Article 823, paragraphs (1), (3) and (7) are amended as follows:

"Art. 823. - (1) In cooperation with the European Medicines Agency, the National Agency for Medicines and Medical Devices ensures that the legal requirements governing medicinal products are complied with, by means of inspections, if necessary unannounced and, where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose and certified/recognized by the National Agency for Medicines and Medical Devices to carry out tests on medicine samples. This cooperation shall consist in sharing information with the European Medicines Agency both inspections that are planned and that have been conducted. The National Agency for Medicines and Medical Devices and the

European Medicines Agency cooperate in the coordination of inspections in third countries. The National Agency for Medicines and Medical Devices may also carry out unannounced inspections at the premises of manufacturers of active substances used as starting materials, or at the premises of marketing authorisation holders whenever it considers that there are grounds for suspecting non-compliance with the principles and guidelines of good manufacturing practice referred to in Article 756. The National Agency for Medicines and Medical Devices may carry out inspections of starting material manufacturers at the specific request of the manufacturers themselves. Such inspections shall be carried out by inspectors of the National Medicines Agency, who shall be empowered to:

a) inspect the manufacturing or commercial establishments of manufacturers of medicinal products or of active substances used as starting materials, and any laboratories employed by the holder of the manufacturing authorisation to carry out checks pursuant to Article 725;

b) take samples including with a view to independent tests being carried out by a control laboratory of the National Agency for Medicines and Medical Devices or a laboratory certified/recognized by the National Agency for Medicines and Medical Devices; the cost of the samples taken during supervision activities shall be covered, as appropriate, by either the manufacturer or the distribution unit; the cost of tests carried out by the National Agency for Medicines and Medical Devices or laboratories recognized by the National Agency for Medicines and Medical Devices shall be covered from the either the budget of the National Agency for Medicines and Medical Devices, if the product complies with qualitative requirements, or by the manufacturer or distributor in infringement, if the product does not comply with qualitative requirements;

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

d) inspect the premises, records and documents of marketing authorisation holders or any firms employed by the marketing authorisation holder to perform the activities described in Chapter 10 of this Title.

.....

(3)

.....

After every inspection as referred to in (1), the inspectors of the National Agency for Medicines and Medical Devices shall report on whether the manufacturer complies with the principles and guidelines of good manufacturing practice laid down in Article 756 and 795 or whether the marketing authorisation holder complies with the requirements laid down in Chapter X of this Title. The National Agency for Medicines and Medical Devices communicates the content of those reports to the inspected entity. Before adopting the report, the National Agency for Medicines and Medical Devices give the inspected entity concerned the opportunity to submit comments.

(7) If the outcome of the inspection as referred to in (1), a), b) and c) or the outcome of an inspection of a distributor of medicinal products or active substances or a manufacturer of excipients used as starting materials is that the inspected entity does not comply with the legal requirements and/or the principles and guidelines of good manufacturing practice or good distribution practices as provided for by Union law, the information shall be entered in the Union database as provided for in paragraph (6).”

76. **Under Article 823, a new paragraph, (9), is inserted after (8), reading:**

"(9) If the outcome of the inspection referred to under (1), d) is that the marketing authorisation holder does not comply with the pharmacovigilance system as described in the pharmacovigilance system master file and with Chapter X of this Title, the National Agency

for Medicines and Medical Devices shall bring the deficiencies to the attention of the marketing authorisation holder and give him the opportunity to submit comments. In such case, the National Agency for Medicines and Medical Devices informs the other Member States, the European Medicines Agency and the European Commission. Where appropriate, the National Agency for Medicines and Medical Devices takes the necessary measures to ensure that a marketing authorisation holder is subject to effective, proportionate and dissuasive penalties."

77. Article 828 is amended as follows:

"Art. 828. - The National Agency for Medicines and Medical Devices shall suspend, revoke or vary a marketing authorisation if the view is taken that the medicinal product is harmful or that it lacks therapeutic efficacy, or that the risk-benefit balance is not favourable, or that its qualitative and quantitative composition is not as declared. Therapeutic efficacy shall be considered to be lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product.

A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as provided for in Articles 702, 704, 705, 706, 707 or 708 are incorrect or have not been amended in accordance with 728, or where any conditions referred to in Articles 726^{1}, 727 or 727^{1} have not been fulfilled or where the controls referred to in Article 824 have not been carried out."

78. Article 829 is amended as follows:

"Art. 829. - (1) In line with measures mentioned under Article 828, the National Agency for Medicines and Medical Devices shall take all appropriate steps to ensure that the supply of the medicinal product is prohibited and the medicinal product withdrawn from the market, if the view is taken that:

a) the medicinal product is harmful; or

b) it lacks therapeutic efficacy; or

c) the risk-benefit balance is not favourable; or

d) its qualitative and quantitative composition is not as declared; or

e) the controls on the medicinal product and/or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled.

(2) The National Agency for Medicines and Medical Devices may limit the prohibition to supply the product, or its withdrawal from the market, to those batches which are the subject of dispute.

(3) For a medicinal product for which the supply has been prohibited or which has been withdrawn from the market in accordance with paragraphs (1) and (2), in exceptional circumstances during a transitional period, the National Agency for Medicines and Medical Devices may allow the supply of the medicinal product to patients who are already being treated with the medicinal product."

79. Article 839, (2) is amended as follows:

"(2) Upon reasoned request, Member States shall send electronically the reports referred to in Article 823 (3) to the competent authority of another Member State or to the European Medicines Agency."

80. Article 840, (4) is amended as follows:

"(4) The National Agency for Medicines and Medical Devices takes account of the annual list made public by the European Medicines Agency concerning medicinal products for which marketing authorisations have been refused, revoked or suspended, whose supply has been prohibited or which have been withdrawn from the market."

81. Paragraphs (2) and (3) of Article 844 are amended as follows:

"(2) When The National Agency for Medicines and Medical Devices avails itself of this possibility, it shall adopt the necessary measures in order to ensure that the requirements of this Title are complied with, in particular those referred to in chapters V, VI, VIII, X and XII of this Title. The National Agency for Medicines and Medical Devices may decide Article 773 (1) and (2) do not apply to medicinal products authorised under paragraph (1).

(3) Before granting such a marketing authorisation, the National Agency for Medicines and Medical Devices takes the following steps:

a) notify the marketing authorisation holder, in the Member State in which the medicinal product concerned is authorised, of the proposal to grant a marketing authorisation under this Article in respect of the medicinal product concerned;

b) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 21 (4) of Directive 2001/83/EC and of the marketing authorisation in force in respect of the medicinal product concerned.

If so requested, the competent authority in that Member State shall supply, within 30 days of receipt of the request, a copy of the assessment report and the marketing authorisation in respect of the medicinal product concerned."

82. Article 847 is amended as follows:

"Art. 847. - For medicinal products authorised through centralised procedure, the National Agency for Medicines and Medical Devices implements conditions or restrictions provided for in decisions of the European Commission addressed to the Member States for the implementation of those conditions or restrictions."

83. The mention on transposition of Community legislation after Article 862 is amended as follows:

"Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003, on standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, amending Directive 2001/83/EC as published in OJ no. L 33 of 8 February 2003, Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, on traditional herbal drugs, Directive 2001/83/EC on the Community code relating to medicinal products for human use, published in

the Official Journal of the European Union no. L 136 of 30 April 2004, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code related to medicinal products for human use, published in the Official Journal of the European Union no. L 136 of 30 April 2004, Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive2001/82/EC and Directive 2001/83/EC **as regards variations to the terms of marketing authorisations for medicinal products,** published in the Official Journal of the European Union no. L 168 of 30 June 2009 and Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use, published in The Official Journal of the European Union no. L 384/74 of 31 December 2010".

Art. II. - Article 5^2 of Government Ordinance No. 70/2002 on the administration of public healthcare units of county and local interest, published in the Official Gazette of Romania, Part I, No. 648 of 31 August 2002, approved as amended through Law No. 99/2004, as amended, is modified and shall read as follows:

"Art. 5^2. - (1) Multi-functional healthcare centres may be established, in accordance with the law, at the proposal of the managing authorities in the hospital field, as non-legal units, incorporated in county/town/city hospitals, in order to ensure a set of medical services adapted to the needs of local communities.

(2) Multi-functional health centres stipulated in Art. (1) may also be founded by the organisation of public health units with beds, following the abolition of such units through Government Decision, in accordance with the Law.

(3) Local public administration authorities may also found multi-functional healthcare centres, as legal healthcare units, through an administrative action taken by the head of the local public administration authority, with the assent of the Ministry of Health and of the Ministry of Administration and Internal Affairs.

(4) The abolition of legal multifunctional healthcare centres is approved through an administrative action taken by the head of the local public administration authority, with the assent of the Ministry of Health and of the Ministry of Administration and Internal Affairs.

(5) The specialised healthcare personnel and the auxiliary personnel from public healthcare units with beds, specified in paragraph (2), shall be assimilated by county, town or city hospitals in which multi-functional healthcare centres are founded in accordance with the needed human resources, depending on the number of jobs approved in accordance with the law. The personnel who have not been assimilated shall be assigned to other healthcare units, in accordance with the conditions established through a Minister of Health Order.

(6) Legal/non-legal multi-functional health centres may include:

a) specialised offices;

b) between 5 and 20 hospital beds per day;

c) medical analysis, radiology and medical imaging laboratories;

d) other medical structures without beds, for continuous hospitalisation.

(7) The organisational structure of county, town or city hospitals which include multi-functional healthcare centres regulated by this ordinance is approved, in accordance with the provisions of Art. 174 (4) or (5) of Law No. 95/2006, as amended.

(8) The organisational structure and amendment of the structure of juridical multi-functional healthcare centres are approved through an official order of the Head of the local public administration authority, with the assent of the Ministry of Health.

(9) The multi-functional healthcare centre is managed by a director/contract staff, job obtained by contest/exam and remunerated in accordance with the law.

(10) Financing of non-juridical multi-functional healthcare centres is done in accordance with the provisions of Chapter IV of Title VII of Law No. 95/2006, as amended.

(11) Financing of juridical multifunctional health centres is done in accordance with the conditions established through a frame agreement on the conditions for granting medical assistance in the context of the social health insurance system and its enforcement guidelines.

(12) Local public administration authorities grant the money needed for expenses such as for administrative and operational purposes, reparations, consolidation, extension and modernization of multi-functional healthcare centres, within the limits of budget credits approved for this purpose within local budgets.

(13) As regards legal multi-functional healthcare centres, local public administration authorities grant the fees needed for the expenses specified in paragraph (12), as well as other sums for endowment with medical equipment and devices, within the limits of budget credits approved for this purpose within local budgets.

(14) Legal multifunctional healthcare centres may obtain additional incomes from:

a) donation and sponsorship;

b) legacies;

c) co-payment for certain medical services;

d) other sources in accordance with the law."

Art. III. - (1) The dispositions stipulated in Art. 815 (3) b) of Law No. 95/2006, as amended, are also applicable to the holders of the marketing authorizations issued prior to the coming into force of this Emergency Ordinance, starting with the date of renewal of the

marketing authorisation, but no later than 3 years from the entering into force of this Emergency Ordinance.

(2) The National Agency for Medicines and Medical Devices assesses the electronic transmission of the information related to suspected adverse reactions to the EudraVigilance database, in accordance with Art. 819 (3) of Law No. 95/2006, as amended. The transmission of such information is performed by Marketing Authorisation Holders within 6 months from EMA's notification concerning the functionality of the EudraVigilance database.

(3) Until the European Medicines Agency is able to ensure the functionality of EudraVigilance database in accordance with Art. 24 of Regulation (EC) No. 726/2004, MAHs shall report to the National Agency for Medicines and Medical Devices, 15 days after the concerned Holder has been informed about the event, all serious suspected adverse reactions having occurred on Romanian territory. Marketing Authorisation Holders must report all serious adverse reactions occurring on the territory of a third country to the European Medicines Agency and to the competent authorities in the Member States where the product is authorised, if required.

(4) Until the European Medicines Agency is able to ensure the functionality of EudraVigilance database in accordance with Art. 24 of Regulation (EC) No. 726/2004, the National Agency for Medicines and Medical Devices may require the MAHs to report, in 90 days after the date on which the concerned Holder has been informed about the event, all non-serious suspected adverse reactions occurring on Romanian territory.

(5) Until the European Medicines Agency is able to ensure the functionality of EudraVigilance database in accordance with Art. 24 of Regulation (EC) No. 726/2004, the National Agency for Medicines and Medical Devices shall make sure that the reports mentioned in paragraph (4) about the events which have occurred on its premises are immediately made available in the EudraVigilance database, no later than 15 days after MAH's reporting of serious adverse reactions.

(6) As regards the Marketing Authorisation Holder's obligation to forward Periodic Safety Update Reports (PSURs) to the European Medicines Agency, in accordance with Art. 819^2 (1) of Law No. 95/2006, as amended, the National Agency for Medicines and Medical Devices makes sure that the obligation is fulfilled in 12 months following the assessment of the European electronic depot's functionality and EMA's notification about this matter. Until the European Medicines Agency can grant the European electronic depot's functionality for PSURs, Marketing Authorisation Holders shall forward Periodic Safety Update Reports (PSURs) to all competent authorities in the Member States where the product has been authorised for marketing.

PRIME MINISTER
VICTOR-VIOREL PONTA

Countersigned:
Minister of Health,
Vasile Cepoi
Minister of Administration and Internal Affairs,
Ioan Rus
Minister-delegate for administration,
Victor Paul Dobre
Minister of Labour, Family and Social Protection

Mariana Câmpeanu
Minister of European Affairs,
Leonard Orban
Minister of Education, Research, Youth and Sports
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Liviu Marian Pop
Vice prime minister,
Minister of Public Finances,
Florin Georgescu

Bucharest, 27 June 2012.
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