MALVINA HOXHA ◆ LINDA PUSTINA ◆ PAOLA MINGHETTI

A comparison of

THE ALBANIAN PHARMACEUTICAL LEGISLATION

with

THE EUROPEAN PHARMACEUTICAL DIRECTIVES

and

THE ITALIAN PHARMACEUTICAL LEGISLATION

FrancoAngeli

Informazioni per il lettore

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* Chapter IX of the decree 219/06 is revoked and is not included in this book (see above).

Preface

The scope of this book is to compare the actual Albanian pharmaceutical legislation 105/2014 and the law Nr. 9323 date 25.11.2004. For medicinal products and pharmaceutical service" with both the European pharmaceutical directive, 2001/83/CE and further modifications (Directive 2002/98/CE, 2003/63/CE, 2004/24/CE, 2004/27/CE, 2008/29/CE, 2009/53/CE, 2009/120/CE, 2010/84/CE, 2011/62/CE, 2012/26/CE, (CE) Regulation n.1901/2006, (CE) Regulation n. 1394/2007) and part of the Directive 2003/94/CE, with the current Italian pharmaceutical legislation (Legislative Decree 219/06 modified by Legislative Decree no. 274/2007, Decree Law no. 158/2012, Law no. 228/2012, Legislative Decree no. 17/2014, Legislative Decree no. 42/2014, Decree Law no. 78/2015, Law no. 166/2016, Legislative Decree no. 117/2017, Law 124/2017).

The pharmacovigilance is regulated by the Decree 219/06, Law no. 228/2012, by the Ministerial Decree of 30 April 2015, and by the following Regulations: Regulation CE 726/2004 modified and integrated by the Regulations no. 1235/2010, 1027/2012 and 520/2012, and by two other complementary Regulations respectively no. 198/2013 and 658/2014. However, the pharmacovigilance chapter is not included in this book as the chapter IX of the decree 219/06 is revoked.

The directive on clinical trial and regulation on supplementary protection certificate for medicinal products is not inserted in this book.

The comparison of the respective pharmaceutical legislations it is necessary to assess the role of the European pharmaceutical directive in respect to the national directives. In addition, this comparison can have a role in further changes of the current national pharmaceutical legislation, adapting to the European pharmaceutical directive. This book will contribute in expanding the knowledge on the EU directives on pharmaceutical legislation and best practices in EU countries on the respective fields contributing to a complete harmonization of the legislations.

The authors would like to thank Mariangela Denise Bonotti for her cooperation.

In the text the following European directives or Regulations are indicated as follows:

B: Directive 2001/83/CE; **M1** : Directive 2002/98/CE; **M2**: Directive 2003/63/CE; **M3**: Directive 2004/24/CE; **M4:** Directive 2004/27/CE; **M5**: Regulation (CE) n.1901/2006; **M6**: Regulation (CE) n. 1394/2007; **M7**: Directive 2008/29/CE; **M8**: Directive 2009/53/CE; **M9**: Directive 2010/84/CE; **M10**: Directive 2011/62/CE; **M11**: 2012/26/CE; **M12:** Directive 2009/120/CE

The Italian Legislative Decree, Decree-Law, or Laws are indicated as follows: **D**: Legislative Decree 219/06, 24 April 2006; **D1:** Law no. 274, date, 29.12.2007; **D2:** Determina AIFA, date 25.08.2011, modification of the legislative decree nr. 219, date 24.04. 2006; **D3:** Law no. 17, 19.02.2014; **D4:** Law no. 42, date 4.03.2014; **D5**: Law no. 88 of 7 July 2009; **D6:** Decree Law no. 158/2012; **D7:** Decree Law no. 78/2015; **D8:** Law no. 166/2016; **D9:** Legislative Decree no. 117/2017; **D10:** Law no. 124/2017, date 4 august 2017.

The Albanian Pharmaceutical legislation 105/2014 modified by Law Nr 109/2015, 15.10.2015 is reported in the text in black color; the VKM 299, date 8.4.2015, amended by VKM nr. 790 date 22.9.2015, VKM nr. 432 date 6.6.2016, VKM nr.579 date 3.10.2018 is reported in red color, and the Decree nr 359, date 29.04.2015 is reported in blue color.

I. DEFINITIONS

LAW Nr. 105/2014, AMENDED BY LAW NR 109/2015, 15.10.2015 VKM 299, date 8.4.2015, amended by VKM nr. 790 date 22.9.2015, VKM nr. 432 date 6.6.2016, VKM nr.579 date 3.10.2018	DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND FURTHER CHANGES Directive 2017/1572 (EU) of the European Commisssion supplementing the Directive 2001/83/EC as regards the principles and guidelines of good manufacturing practice for medicinal products for human use	LEGISLATIVE DECREE NO.219 OF 24.4.2006 AND FURTHER CHANGES
TITLE I Definitions	**TITLE I Definitions**	**TITLE I Definitions**
Article 3 *Definitions*	**Article 1**	**Article 1** *Definitions*
In this law, the following terms have the following meanings:	For the purposes of this Directive, the following terms shall bear the following meanings:	For the purposes of this Directive, the following terms shall bear the following meanings:
	▼ M4	
5."Medicinal product"	2. Medicinal product:	a. Medicinal product:
is any substance or combination of substances: a) used for the treatment or prevention of diseases in human beings;	(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or	(1) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;
b) administered in human beings, in order to perform a medical diagnosis or restoring, correcting or modifying their physiological functions.	(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.	(2) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
	▼ B	
47. Substance:	3. Substance:	b. Substance:
Any substance irrespective of origin which may be:	Any matter irrespective of origin which may be:	Any matter irrespective of origin which may be:
a) human, eg human blood or human blood products;	– human, e.g. human blood and human blood products;	1) human, e.g. human blood and human blood products;
b) animal, eg, microorganisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;	– animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;	2)animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;
c) vegetables, for example, microorganisms, plants, parts of plants, plant secretions, extracts;	– vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts;	3) vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts;

LAW Nr. 105/2014, AMENDED BY LAW NR 109/2015, 15.10.2015	DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND FURTHER CHANGES	LEGISLATIVE DECREE NO.219 OF 24.4.2006 AND FURTHER CHANGES
ç) chemical, eg , elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.	– chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.	4)chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;
	▼ M11	▼ D3
48. "Active substance"	3a. Active substance:	b-bis) Active substance:
is any substance or mixture of substances, which are used in the manufacture of medicinal products and exert pharmacological, immunological or metabolic effect, with the purpose of performing a medical diagnosis or restoring, correcting, or modifying physiological functions in human beings.	Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.	any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring correcting or modifying physiological functions or to make a medical diagnosis.
49. Excipient:	3b. Excipient:	b ter) Excipient:
Is any constituent of a medicinal product other than the active substance part of the formulation of the pharmaceutical form of the medicinal product.	Any constituent of a medicinal product other than the active substance and the packaging material.	Any constituent of a medicinal product other than the active substance and the packaging material.
	▼ B	▼ D
15. Immunological medicinal product:	4. Immunological medicinal product:	c) Immunological medicinal product:
Any medicinal product consisting of vaccines, toxins, serums or allergen products.	Any medicinal product consisting of vaccines, toxins, serums or allergen products:	any medicinal product consisting of vaccines, toxins, serums or allergen products.
	(a) vaccines, toxins and serums shall cover in particular:	The vaccines, toxins and serums shall cover in particular: the agents used to produce active immunity, or passive immunity and the agents used to diagnose the state of immunity.
	(i) agents used to produce active immunity, such as cholera vaccine, BCG, polio vaccines, smallpox vaccine;	
	(ii) agents used to diagnose the state of immunity, including in particular tuberculin and tuberculin PPD, toxins for the Schick and Dick Tests, brucellin;	
	(iii) agents used to produce passive immunity, such as diphtheria antitoxin, anti-smallpox globulin, antilymphocytic globulin;	
	(b) 'allergen product' shall mean any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent.	The allergen product is a medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent;
	▼ M6	▼
	4a. Advanced therapy medicinal product:	c bis. Advanced therapy medicinal product:

LAW Nr. 105/2014, AMENDED BY LAW NR 109/2015, 15.10.2015	DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND FURTHER CHANGES	LEGISLATIVE DECREE NO.219 OF 24.4.2006 AND FURTHER CHANGES
	A product as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products (1).	a product as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products.
	▼ M4	▼ D
17. Homeopathic medicinal product:	5. Homeopathic medicinal product:	d) Homeopathic medicinal product:
Is the medicinal product prepared from homeopathic stock substances in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence of that, by the officially used pharmacopoeias in our country. A homeopathic medicinal product may contain a number of principles.	Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles.	Any medicinal product obtained from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States of the European Union; a homeopathic medicinal product may contain a number of principles;
	▼ B	
	6.Radiopharmaceutical:	e) Radiopharmaceutical:
	Any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose.	Any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose;
---	7. Radionuclide generator:	f) Radionuclide generator:
	Any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other method and used in a radiopharmaceutical.	Any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other method and used in a radiopharmaceutical;
	▼ M4	
	8. Kit:	g) kit:
	Any preparation to be reconsitituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration.	Any preparation to be reconsitituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration.
	9.Radionuclide precursor:	h) Radionuclide precursor:
	Any other radionuclide produced for the radio-labelling of another substance prior to administration	Any other radionuclide produced for the radio-labelling of another substance prior to administration;
---	10. Medicinal products derived from human blood or human plasma: Medicinal products based on blood constitutents which are prepared industrially by public or private establishments, such medicinal products including, in particular, albumin, coagulating factors and immunoglobulins of human origin.	i) Medicinal products derived from human blood or human plasma: Medicinal products based on blood constitutents which are prepared industrially by public or private establishments, such medicinal products including, in particular, albumin, coagulating factors and immunoglobulins of human origin;

LAW Nr. 105/2014, AMENDED BY LAW NR 109/2015, 15.10.2015	DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND FURTHER CHANGES	LEGISLATIVE DECREE NO.219 OF 24.4.2006 AND FURTHER CHANGES
	▼ M10	▼ D5
25. Adverse reaction: The undesired, noxious response of the organism during the administration of a medicinal product in the normal using conditions.	11. Adverse reaction: A response to a medicinal product which is noxious and unintended.	l) Adverse reaction: The noxious and unintended response, as a result not only of an authorized use of medicinal product, in the normal conditions of use, but also of the therapeutic errors, and the non appropriate use in line with the marketing authorization, including the incorrect use and the drug abuse;
	▼ B	▼ D
26. Serious adverse reaction: Is any adverse reaction which results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.	12. Serious adverse reaction: An adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.	m) Serious adverse reaction: An adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.
27. Unexpected adverse reaction: Is any adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.	13. Unexpected adverse reaction: An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.	n) Unexpected adverse reaction: An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.
68. "Updated periodic report of security" is the document that aims to provide an assessment of the balance benefit/ risk of a medicinal product, which is periodically presented to the authorities.		o) "Updated periodic report of security": periodic report which contains the information specified in article 130;
	▼ M10	▼ D5
73. Post-authorisation safety study: Is any study relating to an authorized medicinal product conducted with the aim of identifying or evaluating its safety profile for the human being health, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.	15. Post-authorisation safety study: Any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.	p) Post-authorisation safety study: the study related to an authorised medicinal product conducted to identify, characterize or quantify a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures;
	▼ B	▼ D
	16. Abuse of medicinal products: Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects.	q) Abuse of medicinal products: Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects;
74. Wholesale distribution of medicinal products:	17. Wholesale distribution of medicinal products:	r) Wholesale distribution of medicinal products:
Are all activities consisting of procuring, holding, supplying or exporting medicinal products to the private pharmacies. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or entitled to supply medicinal products to the public in the Republic of Albania.	All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned.	any activity consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public; such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public;

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	▼ M11	▼ D3
	17a. Brokering of medicinal products: All activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person.	r bis) Brokering of medicinal products: any activitiy in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person.
	▼ B	
	18. Public service obligation: The obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.	s) Public service obligation: The obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question; for this purpose can not be taken out from the distribution and sale of drugs on the national territory for which special measures are taken to prevent or limit shortages or unavailability on the market, even temporarily, or in the absence of valid therapeutic alternatives;
	▼ M4	▼ D
59. Representative of the marketing authorisation holder: Is any juridical person, local or foreigner, who has the right of representing the marketing authorization holder in Albania.	18a. Representative of the marketing authorisation holder: The person, commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned.	t) Representative of the marketing authorisation holder: The person, designated by the marketing authorisation holder to represent him in the Member State concerned, as a local representative;
	▼ B	
69. Medicinal Prescription: Is the format approved for the medicinal prescription, printed or electronic, issued by a health professional person qualified to do so. The content and the form of the medicinal prescription are approved from the ministry in charge of health.	19. Medicinal Prescription: Any medicinal prescription issued by a professional person qualified to do so.	u) Medicinal Prescription: Any medicinal prescription issued by a professional person qualified to do so;
	▼ M4	
29. Name of the medicinal product: Is the name, attributed to a medicinal product, which may be either an invented name, scientific, or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.	20. Name of the medicinal product: The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.	v) Name of the medicinal product: The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder;
	▼ B	
30. Common name: The international common name recommended by the World Health Organization, or, if one does not exist, the usual common name.	21. Common name: The international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name.	z) Common name: The international non-proprietary name recommended by the *World Health Organization,* usually in the Italian official version or, if this version is not yet available, in the English version; only in case that does not exist, the usual common name is used.

LAW Nr. 105/2014, AMENDED BY LAW NR 109/2015, 15.10.2015	DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND FURTHER CHANGES	LEGISLATIVE DECREE NO.219 OF 24.4.2006 AND FURTHER CHANGES
22. Dose of the medicinal product: Is the content of the active substances expressed quantitatively per unit, per unit of volume or weight, according to the presentation of the medicinal product.	22. Strength of the medicinal product: The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.	aa) Strength of the medicinal product: The content of the active substances expressed according to the pharmaceutical form quantitatively per dosage unit, per unit of volume or weight;
52. Primary packaging: Is any form of the packaging in direct contact with the medicinal product.	23. Immediate packaging: The container or other form of packaging immediately in contact with the medicinal product.	bb) Immediate packaging: The container or other form of packaging immediately in contact with the medicinal product;
53. Outer packaging: The packaging into which is placed the primary packaging.	24. Outer packaging: The packaging into which is placed the immediate packaging.	cc) Outer packaging or secondary packaging: The packaging into which is placed the immediate packaging;
31. Labelling: Is the information on the primary or outer packaging.	25. Labelling: Information on the immediate or outer packaging.	dd) Labelling: Information on the immediate or outer packaging.
35. Package leaflet: Is the leaflet containing information for the user which accompanies the medicinal product that is ready to be used.	26. Package leaflet: A leaflet containing information for the user which accompanies the medicinal product.	ee) Package leaflet: A leaflet containing information for the user which accompanies the medicinal product;
	▼ M4	
1. Agency: the National Agency of the Medicinal Products and Medical Devices (AKBPM)	27. Agency: The European Medicines Agency established by Regulation (EC) No 726/2004 (1).	ff) EMEA (The European Medicines Agency): The European agency for drugs established by Regulation (EC) no. 726/2004 of the European Parliament and the Council, of 31st March, 2004, modified, which establishes the communitary procedures for the authorization and supervision of medicinal product for human and veterinary use and that establishes the European drug agency, as defined below regulation (CE) Nr. 726/2004;
2. Pharmaceutical agency: commercial-health unit where the medicinal products are stored and traded, based on the list approved by the minister responsible for health, according to the definitions made in this law.		
	28. Risks related to use of the medicinal product:	gg) Risks related to use of the medicinal product:
	– any risk relating to the quality, safety or efficacy of the medicinal product as regards of patients' health or public health;	1) any risk relating to the quality, safety or efficacy of the medicinal product as regards of patients' health or public health;
	– any risk of undesirable effects on the environment.	2)any risk of undesirable effects on the environment;
	28a. Risk-benefit balance: An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in point 28, first indent.	hh) Risk-benefit ratio: An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in the letter gg) point 1);

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	▼ M10	▼ D5
77. Risk management system: is the set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise the risk relating to medicinal products, including the assessment of the effectiveness of those activities and interventions.	28b. 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.	c) 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;
65. Risk management plan: is the detailed description of the risk management system.	28c. Risk management plan: a detailed description of the risk management system.	d) Risk management plan: a detailed description of the risk management system;
76. Pharmacovigilance system: is the system used by the marketing authorisation holder and the Agency to fulfil the tasks and responsibilities listed in this law, and those designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance.	28d. Pharmacovigilance system: a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in Title IX and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance.	e) Pharmacovigilance system: a control system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in this law, and designed to monitor the safety of authorised medicinal products and to detect any change to their risk-benefit balance;
	▼ M10	
	28e. 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.	f) 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.
	▼ M3	▼ D
56. Traditional herbal product: Is the herbal product, the effectiveness of which can be recognized on the basis of long-term use in the Republic of Albania, in the European Union, and who fulfills the conditions laid down in this law.	29. Traditional herbal medicinal product: A herbal medicinal product that fulfils the conditions laid down in Article 16a(1).	ii) Traditional herbal or phitoterapeutical medicinal product: A medicinal product that fulfils the conditions laid down in Article 21 poin(1) of this law;
18. Herbal medicinal product: Is the medicinal product, the active ingredient of which, contains one or more herbal substances in combination with one or more herbal preparations.	30. Herbal medicinal product: Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.	ll) Herbal medicinal or phitoterapeutical product: Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more herbal preparations;
Article 30 of Regulation 1. Traditional herbal product is the product containing as active ingredients one or more herbal preparations, combined with one or more herbal preparations.		

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46. Substances of herbal origin: Are the fragmented or whole plant, algae, fungi, lichen, in an unprocessed, usually dried form, but sometimes fresh, which are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).	31. Herbal substances: All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).	mm) Herbal substances: All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);
Article 30 of Regulation 2. Herbal substances are all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).		
54. Herbal preparations: Are the preparations obtained by substances of herbal origin, as a result of extraction, distillation, crushing, fractionation, purification, concentration or fermentation treatments. These include substances of herbal origins powdered, tinctures, extracts, essential oils, exudates, etc.	32. Herbal preparations: Preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.	nn) Herbal preparations: Preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates;
Article 30 of Regulation 3. Herbal preparation is the preparation obtained by subjecting herbal substances to treatments such as extraction, distillation, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, processed juices and exudates.		
	▼ **M11**	▼ **D3**
16. Falsified medicinal product: Is the medicinal product with a false representation of:	33. Falsified medicinal product: Any medicinal product with a false representation of:	nn-bis) Falsified medicinal product: Any medicinal product that does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights, with a false representation of:
(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients, excipients and the concentration of those ingredients;	(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;	1) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the appropriate strength of those ingredients;

LAW Nr. 105/2014, AMENDED BY LAW NR 109/2015, 15.10.2015	DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND FURTHER CHANGES	LEGISLATIVE DECREE NO.219 OF 24.4.2006 AND FURTHER CHANGES
(b) its source, including its manufacturer and country of manufacturing, its country of origin or its marketing authorisation holder;	(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or	2) its source, including its manufacturer, its country of manufacturing, its country of origin and its marketing authorisation holder;
(c) its history, including the records and documents related to the distribution.	(c) its history, including the records and documents relating to the distribution channels used. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.	3) its history, including the records and documents relating to the distribution channels used;
		oo) medical gas: any medicinal product consisting of one or more active substances in gas form, mixed or not with excipients in the form of gas;
1. "Agency" is the National Agency of Medicinal Products and Medical Devices (AKBPM).		pp) AIFA: The Italian Drug Agency established under paragraph 2 of article 48 of Law nr. 269, September 30, 2003, amended by Law no. 326, November 24, 2003;
3. "Marketing Authorization" is the document issued by the Agency, which certifies that the medicinal product meets the standards on safety, quality and efficiency.		qq) AIC: the marketing authorization.
4. "Authorization of use" is the document issued by the Agency, which certifies that the subject that possess it has the right to place the medicinal product in market for use.		
8. "Medicinal products sold without prescription" are medicinal products used for self-medication and are sold and traded at a pharmacy without a doctor prescription (over-the-counter - OTC).		
9. "Production Authorization" is the document issued to the Pharmaceutical Producer by the Minister responsible for Health, upon the proposal of the KVKPB, after this latter has established that the pharmaceutical manufacturer has met all production, quality, storage and distribution standards of the medicinal product.		

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10. "Biological medicinal product" is a medicinal product in which an active substance is a biological substance, a substance that is produced or derived from a biological source and which needs a combination of physical-chemical and biological testing to have the characterization and determining of its quality, simultaneously with the process of its production and control.		
11. "Biosimilar medicinal product" is a similar biological medicinal product or medicinal product of biological origin having the same active ingredient, form and route of administration as the biological reference product, that has been demonstrated through a quality, safety and efficacy program. This medicinal product does not meet the criteria to be called a generic medicinal product due to changes in component and production processes from the reference biological medicinal product and for these reasons it is not replaceable.		
12. "medicinal product for gene therapy" is a biological medicinal product with the following qualities:		
a) contains an active substance, which comprises or consists of a recombinant nucleic acid, used in or administered to human beings, for the purpose of regulating, repairing, replacing, adding, deleting a genetic sequence;		
b) its therapeutic, prophylactic or diagnostic effect is directly related to the recombinant nucleic acid sequence it contains, or to the product of the genetic expression of this sequence;		
c) is different from the vaccine against infectious diseases.		
13. "Somatic cell therapy medicinal product" is the biological medicinal product with the following qualities:		

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a) Contains or consists of cells or tissues that have been subject to considerable manipulation, so that the biological characteristics, physiological functions or respective structural characteristics for the foreseen clinical use have undergone changes; or consists of cells or tissues that are not intended to be used for the same essential function/s of the recipient and donor; b) is presented or used in or administered to human beings for the purpose of the treatment, prevention or diagnosis of a disease by the pharmacological, immunological or metabolic action of its cells or tissues. 14. "Medicinal Product in the Experimental stage" is the pharmaceutical form of an active substance or placebo, which is tested or used as a reference in a clinical trial, including medicinal products possessing a marketing authorization, which are: a) used or prepared (formulated or packaged) in a different manner from the authorized form; b) used for an unauthorized indication; c) used to obtain further information on the authorized form. 19. "Ready-to-use" is the medicinal product that has undergone all the processes of production, packaging and final labeling. 20. "Bioequivalence" (biological equivalence) indicates that two or more preparations containing the same active substance release it in the blood at the same relative speed and in the same amount, giving the same concentrations in the blood when used at the same molar dose of the therapeutic ingredient and under the same experimental conditions as a single or multiple dose. 21. "Clinical Trial Dossier" is a summary of clinical or non-clinical data on the medicinal product in the experimental stage, which are necessary for its study in human beings.		