Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

TITLE I

DEFINITIONS

Article 1

For the purposes of this Directive, the following terms shall bear the following meanings:

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[[F2]2.Medicinal product : (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(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.**]**

3. Substance : Any matter irrespective of origin which may be:

— human, e.g.

human blood and human blood products;

— animal, e.g.

micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;

— vegetable, e.g.

micro-organisms, plants, parts of plants, vegetable secretions, extracts;

— chemical, e.g.

elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.

4. Immunological medicinal product : Any medicinal product consisting of vaccines, toxins, serums or allergen products:

(a) vaccines, toxins and serums shall cover in particular:

(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.

[F3 4a. *Advanced therapy medicinal product*	:	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).**]**
[F2 5. Homeopathic medicinal product	:	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.**]**
6. Radiopharmaceutical	:	Any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose.
7. 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.
8. **[**F2 Kit**]**	:	Any preparation to be reconsitituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration.
9. Radionuclide precursor	:	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.
11. Adverse reaction	:	A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.
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.
13. Unexpected adverse reaction	:	An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.
14. Periodic safety update reports	:	The periodical reports containing the records referred to in Article 104.
15. Post-authorisation safety study	:	A pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or quantifying a safety hazard relating to an authorised medicinal product.
16. Abuse of medicinal products	:	Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effets.
17. Wholesale distribution of medicinal products	:	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.
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.

[[F4]18aRepresentative 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.**]**
19. Medicinal Prescription	:	Any medicinal prescription issued by a professional person qualified to do so.
[[F2]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.**]**
21. Common name	:	The international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name.
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.
23. Immediate packaging	:	The container or other form of packaging immediately in contact with the medicinal product.
24. Outer packaging	:	The packaging into which is placed the immediate packaging.
25. Labelling	:	Information on the immediate or outer packaging.
26. Package leaflet	:	A leaflet containing information for the user which accompanies the medicinal product.
[[F2]27.Agency	:	The European Medicines Agency established by Regulation (EC) No 726/2004[(2)].**]**
[[F2]28.Risks related to use of the medicinal product	:	— any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health; — 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.**]**
[[F5]29.Traditional herbal medicinal product	:	A herbal medicinal product that fulfils the conditions laid down in Article 16a(1).
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.
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).
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.**]**

Textual Amendments

F1 Deleted by 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 relating to medicinal products for human use.

F2 Substituted by 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 relating to medicinal products for human use.

F3 Inserted by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance).

F4 Inserted by 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 relating to medicinal products for human use.

F5 Inserted by Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

(1) **[**[F3]OJ L 324, 10.12.2007, p. 121.**]**

(2) **[**[F2]OJ L 136, 30.4.2004, p. 1.**]**

Textual Amendments

F2 Substituted by 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 relating to medicinal products for human use.

F3 Inserted by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance).