

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...

TITLE II  
SCOPE

Article 2 (1) This Directive shall apply to medicinal products for human...  
Article 3 This Directive shall not apply to: Any medicinal product prepared...  
Article 4 (1) Nothing in this Directive shall in any way derogate...  
Article 5 (1) A Member State may, in accordance with legislation in...

TITLE III  
PLACING ON THE MARKET

CHAPTER 1

Marketing authorization

Article 6 (1) No medicinal product may be placed on the market...  
Article 7 A marketing authorization shall not be required for a radiopharmaceutical...  
Article 8 (1) In order to obtain an authorization to place a...  
Article 9 In addition to the requirements set out in Articles 8...  
Article 10 (1) By way of derogation from Article 8(3)(i), and without...  
Article 10a By way of derogation from Article 8(3)(i), and without prejudice...  
Article 10b In the case of medicinal products containing active substances used...  
Article 10c Following the granting of a marketing authorisation, the authorisation holder...  
Article 11 The summary of the product characteristics shall contain, in the...  
Article 12 (1) The applicant shall ensure that, before the detailed summaries...

## CHAPTER 2

### Specific provisions applicable to homeopathic medicinal products

- Article 13 (1) Member States shall ensure that homeopathic medicinal products manufactured...
- Article 14 (1) Only homeopathic medicinal products which satisfy all of the...
- Article 15 An application for special, simplified registration may cover a series...
- Article 16 (1) Homeopathic medicinal products other than those referred to in...

## CHAPTER 2a

### Specific provisions applicable to traditional herbal medicinal products

- Article 16a (1) A simplified registration procedure (hereinafter ‘ traditional-use registration ’...
- Article 16b (1) The applicant and registration holder shall be established in...
- Article 16c (1) The application shall be accompanied by:
- Article 16d (1) Without prejudice to Article 16h(1), Chapter 4 of Title...
- Article 16e (1) Traditional-use registration shall be refused if the application does...
- Article 16f (1) A list of herbal substances, preparations and combinations thereof...
- Article 16g (1) Articles 3(1) and (2), 4(4), 6(1), 12, 17(1), 19,...
- Article 16h (1) A Committee for Herbal Medicinal Products is hereby established...
- Article 16i Before 30 April 2007, the Commission shall submit a report...

## CHAPTER 3

### Procedures relevant to the marketing authorization

- Article 17 (1) Member States shall take all appropriate measures to ensure...
- Article 18 Where a Member State is informed in accordance with Article...
- Article 19 In order to examine the application submitted in accordance with...
- Article 20 Member States shall take all appropriate measures to ensure that:...
- Article 21 (1) When the marketing authorization is issued, the holder shall...
- Article 22 In exceptional circumstances and following consultation with the applicant, the...
- Article 23 After an authorization has been issued, the authorization holder must,...
- Article 23a After a marketing authorisation has been granted, the holder of...
- Article 23b (1) The Commission shall adopt appropriate arrangements for the examination...
- Article 24 (1) Without prejudice to paragraphs 4 and 5, a marketing...
- Article 25 Authorization shall not affect the civil and criminal liability of...
- Article 26 (1) The marketing authorisation shall be refused if, after verification...

## CHAPTER 4

### Mutual recognition procedure and decentralised procedure

- Article 27 (1) A coordination group shall be set up for the...  
Article 28 (1) With a view to the granting of a marketing...  
Article 29 (1) If, within the period laid down in Article 28(4),...  
Article 30 (1) If two or more applications submitted in accordance with...  
Article 31 (1) The Member States or the Commission or the applicant...  
Article 32 (1) When reference is made to the procedure laid down...  
Article 33 Within 15 days of the receipt of the opinion, the...  
Article 34 (1) The Commission shall take a final decision in accordance...  
Article 35 (1) Any application by the marketing authorization holder to vary...  
Article 36 (1) Where a Member State considers that the variation of...  
Article 37 Articles 35 and 36 shall apply by analogy to medicinal...  
Article 38 (1) The Agency shall publish an annual report on the...  
Article 39 Article 29(4), (5) and (6) and Articles 30 to 34...

## TITLE IV

### MANUFACTURE AND IMPORTATION

- Article 40 (1) Member States shall take all appropriate measures to ensure...  
Article 41 In order to obtain the manufacturing authorization, the applicant shall...  
Article 42 (1) The competent authority of the Member State shall issue...  
Article 43 The Member States shall take all appropriate measures to ensure...  
Article 44 If the holder of the manufacturing authorization requests a change...  
Article 45 The competent authority of the Member State may require from...  
Article 46 The holder of a manufacturing authorization shall at least be...  
Article 46a (1) For the purposes of this Directive, manufacture of active...  
Article 47 The principles and guidelines of good manufacturing practices for medicinal...  
Article 48 (1) Member States shall take all appropriate measures to ensure...  
Article 49 (1) Member States shall ensure that the qualified person referred...  
Article 50 (1) A person engaging in the activities of the person...  
Article 51 (1) Member States shall take all appropriate measures to ensure...  
Article 52 Member States shall ensure that the duties of qualified persons...  
Article 53 The provisions of this Title shall also apply to homeopathic...

## TITLE V

### LABELLING AND PACKAGE LEAFLET

- Article 54 The following particulars shall appear on the outer packaging of...  
Article 55 (1) The particulars laid down in Article 54 shall appear...  
Article 56 The particulars referred to in Articles 54, 55 and 62...  
Article 56a The name of the medicinal product, as referred to in...

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- Article 57 Notwithstanding Article 60, Member States may require the use of...
- Article 58 The inclusion in the packaging of all medicinal products of...
- Article 59 (1) The package leaflet shall be drawn up in accordance...
- Article 60 Member States may not prohibit or impede the placing on...
- Article 61 (1) One or more mock-ups of the outer packaging and...
- Article 62 The outer packaging and the package leaflet may include symbols...
- Article 63 (1) The particulars for labelling listed in Articles 54, 59...
- Article 64 Where the provisions of this Title are not complied with,...
- Article 65 In consultation with the Member States and the parties concerned,...
- Article 66 (1) The outer carton and the container of medicinal products...
- Article 67 The competent authority shall ensure that a detailed instruction leaflet...
- Article 68 Without prejudice to the provisions of Article 69, homeopathic medicinal...
- Article 69 (1) In addition to the clear mention of the words...

## TITLE VI

### CLASSIFICATION OF MEDICINAL PRODUCTS

- Article 70 (1) When a marketing authorization is granted, the competent authorities...
- Article 71 (1) Medicinal products shall be subject to medical prescription where...
- Article 72 Medicinal products not subject to prescription shall be those which...
- Article 73 The competent authorities shall draw up a list of the...
- Article 74 When new facts are brought to their attention, the competent...
- Article 74a Where a change of classification of a medicinal product has...
- Article 75 Each year, Member States shall communicate to the Commission and...

## TITLE VII

### WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS

- Article 76 (1.) Without prejudice to Article 6, Member States shall take...
- Article 77 (1) Member States shall take all appropriate measures to ensure...
- Article 78 Member States shall ensure that the time taken for the...
- Article 79 In order to obtain the distribution authorization, applicants must fulfil...
- Article 80 Holders of the distribution authorization must fulfil the following minimum...
- Article 81 With regard to the supply of medicinal products to pharmacists...
- Article 82 For all supplies of medicinal products to a person authorized...
- Article 83 The provisions of this Title shall not prevent the application...
- Article 84 The Commission shall publish guidelines on good distribution practice. To...
- Article 85 This Title shall apply to homeopathic medicinal products.

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## TITLE VIII ADVERTISING

- Article 86 (1) For the purposes of this Title, ‘advertising of medicinal...  
Article 87 (1) Member States shall prohibit any advertising of a medicinal...  
Article 88 (1) Member States shall prohibit the advertising to the general...

## TITLE VIIIa INFORMATION AND ADVERTISING

- Article 88a Within three years of the entry into force of Directive...  
Article 89 (1) Without prejudice to Article 88, all advertising to the...  
Article 90 The advertising of a medicinal product to the general public...  
Article 91 (1) Any advertising of a medicinal product to persons qualified...  
Article 92 (1) Any documentation relating to a medicinal product which is...  
Article 93 (1) Medical sales representatives shall be given adequate training by...  
Article 94 (1) Where medicinal products are being promoted to persons qualified...  
Article 95 The provisions of Article 94(1) shall not prevent hospitality being...  
Article 96 (1) Free samples shall be provided on an exceptional basis...  
Article 97 (1) Member States shall ensure that there are adequate and...  
Article 98 (1) The marketing authorization holder shall establish, within his undertaking,...  
Article 99 Member States shall take the appropriate measures to ensure that...  
Article 100 Advertising of the homeopathic medicinal products referred to in Article...

## TITLE IX PHARMACOVIGILANCE

- Article 101 The Member States shall take all appropriate measures to encourage...  
Article 102 In order to ensure the adoption of appropriate and harmonised...  
Article 102a The management of funds intended for activities connected with pharmacovigilance,...  
Article 103 The marketing authorization holder shall have permanently and continuously at...  
Article 104 (1) The marketing authorisation holder shall be required to maintain...  
Article 105 (1) The Agency, in collaboration with the Member States and...  
Article 106 (1) In order to facilitate the exchange of information on...  
Article 107 (1) Where, as a result of the evaluation of pharmacovigilance...  
Article 108 The Commission shall adopt any amendments which may be necessary...

## TITLE X

SPECIAL PROVISIONS ON MEDICINAL PRODUCTS  
DERIVED FROM HUMAN BLOOD AND PLASMA

- Article 109 For the collection and testing of human blood and human...  
Article 110 Member States shall take the necessary measures to promote  
Community...

## TITLE XI

## SUPERVISION AND SANCTIONS

- Article 111 (1) The competent authority of the Member State concerned  
shall...  
Article 112 Member States shall take all appropriate measures to ensure  
that...  
Article 113 For the purpose of implementing Article 112, Member States  
may...  
Article 114 (1) Where it considers it necessary in the interests of...  
Article 115 Member States shall take all necessary measures to ensure that...  
Article 116 The competent authorities shall suspend, revoke, withdraw or  
vary a...  
Article 117 (1) Without prejudice to the measures provided for in Article...  
Article 118 (1) The competent authority shall suspend or revoke the  
marketing...  
Article 119 The provisions of this Title shall apply to homeopathic  
medicinal...

## TITLE XII

## STANDING COMMITTEE

- Article 120 The Commission shall adopt any changes which are necessary  
in...  
Article 121 (1) The Commission shall be assisted by the Standing  
Committee...

## TITLE XIII

## GENERAL PROVISIONS

- Article 122 (1) Member States shall take all appropriate measures to ensure...  
Article 123 (1) Each Member State shall take all the appropriate measures...  
Article 124 Member States shall communicate to each other all the  
information...  
Article 125 Every decision referred to in this Directive which is taken...  
Article 126 An authorization to market a medicinal product shall not be...  
Article 126a (1) In the absence of a marketing authorisation or of...  
Article 126b In order to guarantee independence and transparency, the  
Member States...  
Article 127 (1) At the request of the manufacturer, the exporter or...

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- Article 127a When a medicinal product is to be authorised in accordance...  
Article 127b Member States shall ensure that appropriate collection systems are in...

#### TITLE XIV

#### FINAL PROVISIONS

- Article 128 Directives 65/65/EEC, 75/318/EEC, 75/319/EEC, 89/342/EEC, 89/343/EEC, 89/381/EEC, 92/25/EEC, 92/26/EEC, 92/27/EEC,...
- Article 129 This Directive shall enter into force on the twentieth day...
- Article 130 This Directive is addressed to the Member States.

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#### ANNEX I

#### ANALYTICAL, PHARMACOTOXICOLOGICAL AND CLINICAL STANDARDS AND PROTOCOLS IN RESPECT OF THE TESTING OF MEDICINAL PRODUCTS

##### Introduction and general principles

- (1) The particulars and documents accompanying an application for marketing authorisation...
- (2) The particulars and documents shall be presented as five modules:...
- (3) The European Community-CTD-presentation is applicable for all types of marketing...
- (4) In assembling the dossier for application for marketing authorisation, applicants...
- (5) With respect to the quality part (chemical, pharmaceutical and biological)...
- (6) The manufacturing process shall comply with the requirements of Commission...
- (7) All information, which is relevant to the evaluation of the...
- (8) All clinical trials, conducted within the European Community, must comply...
- (9) Non-clinical (pharmaco-toxicological) studies shall be carried out in conformity with...
- (10) Member States shall also ensure that all tests on animals...
- (11) In order to monitor the benefit/risk assessment, any new information...

#### PART I

#### STANDARDISED MARKETING AUTHORISATION DOSSIER REQUIREMENTS

1. MODULE 1: ADMINISTRATIVE INFORMATION
  - 1.1. Table of contents
  - 1.2. Application form
  - 1.3. Summary of product characteristics, labelling and package leaflet
    - 1.3.1. Summary of product characteristics
    - 1.3.2. Labelling and package leaflet
    - 1.3.3. Mock-ups and specimens
    - 1.3.4. Summaries of product characteristics already approved in the Member States...
  - 1.4. Information about the experts
  - 1.5. Specific requirements for different types of applications

- 1.6. Environmental risk assessment
2. MODULE 2: SUMMARIES
  - 2.1. Overall table of contents
  - 2.2. Introduction
  - 2.3. Quality overall summary
  - 2.4. Non-clinical overview
  - 2.5. Clinical overview
  - 2.6. Non-clinical summary
  - 2.7. Clinical Summary
3. MODULE 3: CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL INFORMATION FOR MEDICINAL PRODUCTS...
  - 3.1. Format and presentation
  - 3.2. Content: basic principles and requirements
    - (1) The chemical, pharmaceutical and biological data that shall be provided...
    - (2) Two main sets of information shall be provided, dealing with...
    - (3) This Module shall in addition supply detailed information on the...
    - (4) All the procedures and methods used for manufacturing and controlling...
    - (5) The monographs of the European Pharmacopoeia shall be applicable to...
    - (6) In case where starting and raw materials, active substance(s) or...
    - (7) Where the active substance and/or a raw and starting material...
    - (8) For a well-defined active substance, the active substance manufacturer or...
    - (9) Specific measures concerning the prevention of the transmission of animal...
    - (10) For adventitious agents, information assessing the risk with respect to...
    - (11) Any special apparatus and equipment, which may be used at...
    - (12) Where applicable and if needed, a CE marking which is...
  - 3.2.1. Active substance(s)
    - 3.2.1.1. General information and information related to the starting and raw...
    - 3.2.1.2. Manufacturing process of the active substance(s)
    - 3.2.1.3. Characterisation of the active substance(s)
    - 3.2.1.4. Control of active substance(s)
    - 3.2.1.5. Reference standards or materials
    - 3.2.1.6. Container and closure system of the active substance
    - 3.2.1.7. Stability of the active substance (s)
  - 3.2.2. Finished medicinal product
    - 3.2.2.1. Description and composition of the finished medicinal product
    - 3.2.2.2. Pharmaceutical development
    - 3.2.2.3. Manufacturing process of the finished medicinal product
    - 3.2.2.4. Control of excipients
    - 3.2.2.5. Control of the finished medicinal product
    - 3.2.2.6. Reference standards or materials
    - 3.2.2.7. Container and closure of the finished medicinal product
    - 3.2.2.8. Stability of the finished medicinal product
4. MODULE 4: NON-CLINICAL REPORTS
  - 4.1. Format and Presentation



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- 4.2. Content: basic principles and requirements
  - 4.2.1. Pharmacology
  - 4.2.2. Pharmacokinetics
  - 4.2.3. Toxicology
- 5. MODULE 5: CLINICAL STUDY REPORTS
  - 5.1. Format and Presentation
  - 5.2. Content: basic principles and requirements
    - 5.2.1. Reports of bio-pharmaceutics studies
    - 5.2.2. Reports of studies pertinent to pharmacokinetics using human biomaterials
    - 5.2.3. Reports of human pharmacokinetic studies
    - 5.2.4. Reports of human pharmacodynamic studies
    - 5.2.5. Reports of efficacy and safety studies
      - 5.2.5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed...
      - 5.2.5.2. Study reports of uncontrolled clinical studies reports of analyses of...
    - 5.2.6. Reports of post-marketing experience
    - 5.2.7. Case reports forms and individual patient listings

## PART II

### SPECIFIC MARKETING AUTHORISATION DOSSIERS AND REQUIREMENTS

- 1. WELL-ESTABLISHED MEDICINAL USE
- 2. ESSENTIALLY SIMILAR MEDICINAL PRODUCTS
- 3. ADDITIONAL DATA REQUIRED IN SPECIFIC SITUATIONS
- 4. SIMILAR BIOLOGICAL MEDICINAL PRODUCTS
- 5. FIXED COMBINATION MEDICINAL PRODUCTS
- 6. DOCUMENTATION FOR APPLICATIONS IN EXCEPTIONAL CIRCUMSTANCES
- 7. MIXED MARKETING AUTHORISATION APPLICATIONS

## PART III

### PARTICULAR MEDICINAL PRODUCTS

- 1. BIOLOGICAL MEDICINAL PRODUCTS
  - 1.1. Plasma-derived medicinal product
    - a) Principles
    - b) Content
    - c) Evaluation and Certification
  - 1.2. Vaccines
    - a) Principles
    - b) Content
    - c) Evaluation and Certification
- 2. RADIO-PHARMACEUTICALS AND PRECURSORS

- 2.1. Radio-pharmaceuticals
    - Module 3
    - Module 4
    - Module 5
  - 2.2. Radio-pharmaceutical precursors for radio-labelling purposes
    - Module 3
    - Module 4
    - Module 5
  - 3. HOMEOPATHIC MEDICINAL PRODUCTS
    - Module 3
    - Module 4
  - 4. HERBAL MEDICINAL PRODUCTS
    - Module 3
      - (1) Herbal substances and herbal preparations
      - (2) Herbal Medicinal Products
  - 5. ORPHAN MEDICINAL PRODUCTS
- PART IV
- ADVANCED THERAPY MEDICINAL PRODUCTS
- 1. GENE THERAPY MEDICINAL PRODUCTS (HUMAN AND XENOGENEIC)
    - 1.1. Diversity of gene therapy medicinal products
      - a) Gene therapy medicinal products based on allogeneic or xenogeneic cells...
      - b) Gene therapy medicinal products using autologous human cells
      - c) Administration of ready-prepared vectors with inserted (prophylactic, diagnostic or therapeutic)...
    - 1.2. Specific requirements regarding Module 3
  - 2. SOMATIC CELL THERAPY MEDICINAL PRODUCTS (HUMAN AND XENOGENEIC)
    - Specific requirements for cell therapy medicinal products regarding Module 3
      - 1. Human somatic cells
        - (1) Organs, tissues, body fluids and cells of human origin
        - (2) Cell banking systems
        - (3) Ancillary materials or ancillary medical devices
      - 2. Animal somatic cells (xenogeneic)
        - a) Information on the manufacturing process of the active substance(s) and...
        - b) Characterisation of active substance(s)
        - c) Pharmaceutical development of finished medicinal product
        - d) Traceability
  - 3. SPECIFIC REQUIREMENTS FOR GENE THERAPY AND SOMATIC CELL THERAPY (HUMAN...)
    - 3.1. Module 4
    - 3.2. Module 5
      - 3.2.1. Human pharmacology and efficacy studies
      - 3.2.2. Safety

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4. SPECIFIC STATEMENT ON XENO-TRANSPLANTATION MEDICINAL PRODUCTS

ANNEX II

PART A

Repealed Directives, with their successive amendments (referred to by Article 128)

PART B

Time-limits for transposition into national law (referred to by Article 128)

ANNEX III

CORRELATION TABLE

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- (1) [OJ C 368, 20.12.1999, p. 3.](#)
- (2) Opinion of the European Parliament of 3 July 2001 (not yet published in the Official Journal) and Council Decision of 27 September 2001.
- (3) [OJ 22, 9.2.1965, p. 369/65.](#) Directive as last amended by Directive 93/39/EEC ([OJ L 214, 24.8.1993, p. 22](#)).
- (4) [OJ L 147, 9.6.1975, p. 1.](#) Directive as last amended by Commission Directive 1999/83/EC ([OJ L 243, 15.9.1999, p. 9](#)).
- (5) [OJ L 147, 9.6.1975, p. 13.](#) Directive as last amended by Commission Directive 2000/38/EC ([OJ L 139, 10.6.2000, p. 28](#)).
- (6) [OJ L 142, 25.5.1989, p. 14.](#)
- (7) [OJ L 142, 25.5.1989, p. 16.](#)
- (8) [OJ L 181, 28.6.1989, p. 44.](#)
- (9) [OJ L 113, 30.4.1992, p. 1.](#)
- (10) [OJ L 113, 30.4.1992, p. 5.](#)
- (11) [OJ L 113, 30.4.1992, p. 8.](#)
- (12) [OJ L 113, 30.4.1992, p. 13.](#)
- (13) [OJ L 297, 13.10.1992, p. 8.](#)
- (14) [OJ L 214, 24.8.1993, p. 1.](#) Regulation as amended by Commission Regulation (EC) No 649/98 ([OJ L 88, 24.3.1998, p. 7](#)).
- (15) [OJ L 265, 5.10.1984, p. 1.](#) Directive repealed with effect from 13 May 2000 by Directive 97/43/Euratom ([OJ L 180, 9.7.1997, p. 22](#)).
- (16) [OJ L 246, 17.9.1980, p. 1.](#) Directive as amended by Directive 84/467/Euratom ([OJ L 265, 5.10.1984, p. 4](#)), repealed with effect from 13 May 2000 by Directive 96/29/Euratom ([OJ L 314, 4.12.1996, p. 20](#)).
- (17) [OJ L 250, 19.9.1984, p. 17.](#) Directive as amended by Directive 97/55/EC ([OJ L 290, 23.10.1997, p. 18](#)).
- (18) [OJ L 298, 17.10.1989, p. 23.](#) Directive as amended by Directive 97/36/EC ([OJ L 202, 30.7.1997, p. 60](#)).
- (19) [OJ L 184, 17.7.1999, p. 23.](#)