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

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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

(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
4.2. Content: basic principles and requirements
4.2.1. Pharmacology
4.2.2. Pharmaco-kinetics
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 pharmaco-kinetics using human bio-materials
5.2.3. Reports of human pharmaco-kinetic studies
5.2.4. Reports of human pharmaco-dynamic 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

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

(**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.