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 III

PLACING ON THE MARKET

CHAPTER 1

Marketing authorization

[F1 Article 11

The summary of the product characteristics shall contain, in the order indicated below, the following information:

1. name of the medicinal product followed by the strength and the pharmaceutical form.

2. qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used.

3. pharmaceutical form.

4. clinical particulars:

   4.1. therapeutic indications,

   4.2. posology and method of administration for adults and, where necessary for children,

   4.3. contra-indications,

   4.4. special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons handling such products and administering them to patients, together with any precautions to be taken by the patient,

   4.5. interaction with other medicinal products and other forms of interactions,

   4.6. use during pregnancy and lactation,

   4.7. effects on ability to drive and to 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. major incompatibilities,

   6.3. shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,

   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, if appropriate.

7. marketing authorisation holder.

8. marketing authorisation number(s).

9. date of the first authorisation or renewal of the authorisation.

10. date of revision of the text.

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

12. for 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 with its specifications.

For authorisations under Article 10, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.

[[F2]For medicinal products included on the list referred to in Article 23 of Regulation (EC) No 726/2004, 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) No 726/2004 and followed by an appropriate standardised explanatory sentence.

For all medicinal products, a standard text shall be included expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national spontaneous reporting system referred to in Article 107a(1). Different ways of reporting, including electronic reporting, shall be available in compliance with the second subparagraph of Article 107a(1).**]]**

Textual Amendments

F1 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.

F2 Inserted by 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 (Text with EEA relevance).