

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 VI

**CLASSIFICATION OF MEDICINAL PRODUCTS**

*Article 70*

1 When a marketing authorization is granted, the competent authorities shall specify the classification of the medicinal product into:

- a medicinal product subject to medical prescription,
- a medicinal product not subject to medical prescription.

To this end, the criteria laid down in Article 71(1) shall apply.

2 The competent authorities may fix sub-categories for medicinal products which are available on medical prescription only. In that case, they shall refer to the following classification:

- [<sup>F1</sup>a medicinal products on medical prescription for renewable or non-renewable delivery;]
- b medicinal products subject to special medical prescription;
- [<sup>F1</sup>c medicinal products on ‘restricted’ medical prescription, reserved for use in certain specialised areas.]

**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.](#)

*Article 71*

1 Medicinal products shall be subject to medical prescription where they:

- are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or
- are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or
- contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or
- are normally prescribed by a doctor to be administered parenterally.

2 Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:

- the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions in force, such as the United Nations Conventions of 1961 and 1971, or
- the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes, or
- the medicinal product contains a substance which, by reason of its novelty or properties, could be considered as belonging to the group envisaged in the second indent as a precautionary measure.

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3 Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:

- the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments which can only be followed in a hospital environment,
- the medicinal product is used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere, or
- the medicinal product is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

4 A competent authority may waive application of paragraphs 1, 2 and 3 having regard to:

- a the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; and/or
- b other circumstances of use which it has specified.

5 If a competent authority does not designate medicinal products into sub-categories referred to in Article 70(2), it shall nevertheless take into account the criteria referred to in paragraphs 2 and 3 of this Article in determining whether any medicinal product shall be classified as a prescription-only medicine.

#### *Article 72*

Medicinal products not subject to prescription shall be those which do not meet the criteria listed in Article 71.

#### *Article 73*

The competent authorities shall draw up a list of the medicinal products subject, on their territory, to medical prescription, specifying, if necessary, the category of classification. They shall update this list annually.

#### *[<sup>F1</sup>Article 74*

When new facts are brought to their attention, the competent authorities shall examine and, as appropriate, amend the classification of a medicinal product by applying the criteria listed in Article 71.]

#### **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.](#)

#### *[<sup>F2</sup>Article 74a*

Where a change of classification of a medicinal product has been authorised on the basis of significant pre-clinical tests or clinical trials, the competent authority shall not refer to the results of those tests or trials when examining an application by another applicant for or holder of marketing authorisation for a change of classification of the same substance for one year after the initial change was authorised.]

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**Textual Amendments**

- F2** 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.](#)

*Article 75*

Each year, Member States shall communicate to the Commission and to the other Member States, the changes that have been made to the list referred to in Article 73.