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 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.

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.