

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**

[<sup>F1</sup>CHAPTER 2a

**Specific provisions applicable to traditional herbal medicinal products**

*[<sup>F1</sup>Article 16d*

1 Without prejudice to Article 16h(1), Chapter 4 of Title III shall apply by analogy to registrations granted in accordance with Article 16a, provided that:

- a a Community herbal monograph has been established in accordance with Article 16h(3), or
- b the herbal medicinal product consists of herbal substances, preparations or combinations thereof contained in the list referred to in Article 16f.

2 For other herbal medicinal products as referred to in Article 16a, each Member State shall, when evaluating an application for traditional-use registration, take due account of registrations granted by another Member State in accordance with this chapter.]

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**Textual Amendments**

- F1** Inserted by [Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.](#)