

Traditional herbal medicinal products

2002/0008(COD) - 31/03/2004 - Final act

PURPOSE : to establish a harmonised legislative framework for traditional herbal medicinal products.

LEGISLATIVE ACT : Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use. **CONTENT** : this Directive aims to guarantee a high level of health protection for European patients by giving them access to medicines of their choice, provided all the necessary safeguards are met. It will also ensure a single market for traditional herbal medicines by introducing harmonised rules and procedures and encouraging cross-border trade in these products, which at the moment is very limited. This Directive also provides for a simplified registration system for traditional herbal products. The quality requirements which will have to be met are the same as those for all medicinal products. However, to avoid unnecessary testing and burdens on firms, the legislation foresees that new pre-clinical and clinical trials will not be necessary when sufficient knowledge already exists about a particular product. **ENTRY INTO FORCE** : 30/04/2004. **IMPLEMENTATION** : 30/10/2005.