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Herbal medicinal products: bridging the gap between traditional usage and European regulation

The European legislation for pharmaceutical products for human use applies to approval of medicinal products in all EC/EEC countries. Herbals are still a popular treatment alternative in Europe, but the existing legislation was not adjusted to the challenges in approval of these product. In order to harmonize, a simplified registration procedure was suggested by the Commission, and a directive (2004/24/EC) was introduced. Through the provisions of the legislation, challenges in establishing the required safety and efficacy documentation for herbal products are solved. Herbal products are regulated in different European member states either predominantly as medicinal products, food supplements or medicinal devises. This presentation describes how the directive and the Community monographs simplify the work for national agencies and industry and how knowledge about traditional herbal medicinal products can enable safer choices and bridge the gap between tradition and documented effects.