TABLE 10.1 (*Continued*)

Herbal Drug Approval Rules in Different Countries

England	England generally follows the rule of prior use, which says that hundreds of years of use with apparent positive effects and no evidence of detrimental side effects are enough evidence—in lieu of other scientific data—that the product is safe. To promote the safe use of herbal remedies, the Ministry of Agriculture, Fisheries, and Food and the Department of Health jointly established a database of adverse effects of nonconventional medicines at the National Poisons Unit. These products are distinguished from approved pharmaceutical drugs by labels stating, "Traditionally used for…" Consumers understand this to mean that indications are based on historical evidence and have not necessarily been confirmed by modern scientific experimentation.
Europe	Drug approval considerations in Europe are the same as those for new drugs in the United States, where drugs are documented for safety, effectiveness, and quality. But historically, Europeans have been more understanding of the value of phytomedicines, and as a result, it is cheaper to secure approval of phytomedicines specially if there is a long history of their anecdotal use. The EEC, recognizing the need to standardize approval of herbal medicines, developed a series of guidelines, The Quality of Herbal Remedies Directive (EEC Directive, 75/318/EEC, adopted in November 1988) outlines standards for quality, quantity, and production of herbal remedies and provides labeling requirements that member countries must meet. The EEC guidelines are based on the principles of the WHO's Guidelines for the Assessment of Herbal Medicines (1991). According to these guidelines, a substance's historical use is a valid way to document safety and efficacy in the absence of scientific evidence to the contrary. The guidelines suggest the following as a basis for determining product safety: A guiding principle should be that if the product has been traditionally used without demonstrated harm, no specific restrictive regulatory action should be undertaken, unless new evidence demands a revised risk-benefit assessment. Prolonged and apparently uneventful use of a substance usually offers testimony of its safety. With regard to efficacy, the guidelines state the following: For treatment of minor disorders and for nonspecific indications, some relaxation is justified in the requirements for proof of efficacy, taking into account the extent of traditional use; the same considerations may apply to prophylactic use (WHO, 1991). The WHO guidelines give further advice for basing approval on existing monographs: If a pharmacopoeia monograph exists, it should be sufficient to make reference to this monograph. If no such monograph is available, a monograph must be supplied and should be set out in the same way as in an official pharmacopoeia. To further the standardization effort and to increase European scientific support, the phytotherapy societies of Belgium, France, Germany, Switzerland, and the United Kingdom founded the ESCOP. ESCOP's approach to eliminating problems of differing quality and therapeutic use within EEC is to build on the German scientific monograph system to create "European" monographs. In Europe, herbal remedies fall into three categories. The most rigorously controlled are the prescription drugs, which include injectable forms of phytomedicines and those used to treat life-threatening diseases. The second category is OTC phytomedicines, similar to American OTC drugs. The third category is traditional herbal remedies, products that typically have not undergone extensive clinical testing but are judged safe on the basis of generations of use without serious incident.

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