

TABLE 10.1 (Continued)

Herbal Drug Approval Rules in Different Countries

France	<p>Approximately 200 herbs are approved as OTC in France with varying claims. Licensing approval for phytomedicines is subject to regulations generally required for all drugs. There is only one type of license, but for some plant drugs and preparations, this license is granted on the basis of an adapted documentation and an abridged application. In 1990, 115 herbs plus 31 laxatives were involved in this approval procedure. Currently, about 205 herbal drugs are listed. France, where traditional medicines can be sold with labeling based on traditional use, requires licensing by the French Licensing Committee and approval by the French Pharmacopoeia Committee.</p>
Germany	<p>Germany's Commission E (phytotherapy and herbal substances) was established in 1978. It is an independent division of the German Federal Health Agency that collects information on herbal medicines and evaluates them for safety and efficacy. The following methods and criteria are followed by Commission E: (i) traditional use; (ii) chemical data; (iii) experimental, pharmacological, and toxicological studies; (iv) clinical studies; (v) field and epidemiological studies; (vi) patient case records submitted from physician's files; and (vii) additional studies, including unpublished proprietary data submitted by manufacturers. Two kinds of monographs are prepared: monopreparations and fixed combinations. The composition of Commission E is as follows: physicians, pharmacists, pharmacologists, toxicologists, industry representatives, and laypersons, for a total of 24 members. Three possibilities for marketing herbal drugs exist: (i) temporary marketing authorization for old herbal drugs until they are evaluated for safety and efficacy; (ii) monographs of standardized marketing authorization; and (iii) individual marketing authorization. Evaluations are published in the form of monographs that approve or disapprove the herbal drugs for over-the-counter use. Herbal medicines are sold in pharmacies, drug stores, and health food stores. Some herbal medicines are controlled by a physician's prescription. Commission E has published about 300 monographs: 200 "positives" and 100 "negatives." About 600–700 plants are sold in Germany. Approximately 70% of physicians prescribe registered herbal drugs. Part of the annual sales is paid for by government health insurance. Germany considers whole herbal products as a single active ingredient; this makes it simpler to define and approve the product. The German Federal Health Office regulates such products as ginkgo and milk thistle extracts by using a monograph system that results in products whose potency and manufacturing processes are standardized. The monographs are compiled from scientific literature on a particular herb in a single report and are produced under the auspices of the Ministry of Health Committee for Herbal Remedies (Kommission E). Approval of such remedies requires more scientific documentation than traditional remedies, but less than new pharmaceutical drug approvals.</p>
India	<p>India has thousands of years of history of use of ayurvedic medicine; almost 70%–80% of the rural population of India depends on this mode of traditional medicine; no significant control on quality of drug of botanical origin exists in India.</p>
Japan	<p>Traditional Japanese medicine, called kampo, is similar to and historically derived from Chinese medicine but includes traditional medicines from Japanese folklore. Kampo declined when Western medicine was introduced between 1868 and 1912, but by 1928, it had begun to revive. Today, almost half of Japan's Western-trained medical practitioners prescribe kampo medicines, and Japanese national health insurance pays for these medicines. In 1988, the Japanese herbal medicine industry established regulations to manufacture and control the quality of extract products in kampo medicine. These regulations comply with the Japanese government's Regulations for Manufacturing Control and Quality Control of Drugs.</p>

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