

than the first-century AD, focuses on the description of individual herbs. It includes 252 botanical substances, 45 mineral substances, and 67 animal-derived substances. Traditional Chinese medicine was brought to Japan via Korea, and Chinese-influenced Korean medicine was adapted by the Japanese during the reign of Emperor Ingyo (411–453 AD).

In North America, early explorers traded knowledge with the Native American Indians. In 1716, French explorer Lafitau found a species of ginseng, *Panax quinquefolius* L., growing in Iroquois territory in the New World. This American ginseng soon became an important item in world herb commerce. The Jesuits dug up the plentiful American ginseng, sold it to the Chinese, and used the money to build schools and churches. Even today, American ginseng is a sizable crude U.S. export. Although herbal medicines played a significant role in the lives of Americans, they have lost touch with it with the onslaught of allopathic medicines. One of the most significant reports on the use of botanical drugs in North America is the Baseline Natural Health Products Survey among consumers, March 2005, conducted by Health Canada. This survey concluded that 71% use botanical—38% use it on a daily basis, 37% seasonally, and 11% weekly—57% use vitamins, 15% use Echinacea, and 11% use other herbal remedies and algal and fungal products. Almost 80% of North Americans believe that botanical drugs are safer, and their use is likely to increase in the future. However, despite a long history of use, botanical drugs are generally considered to be anecdotal and ineffective by the regulatory agencies and allowed for sale only as food supplements. Recently, this trend of rejecting botanical drugs was reversed, mainly owing to pressures from consumers, and the U.S. Food and Drug Administration (FDA) issued its first botanical guideline and established a separate division within the agency to evaluate and approve botanical products as drugs, both prescription and over the counter (OTC).

10.2 Regulatory Status

The legal process of regulation and legislation of herbal medicines changes from country to country (Table 10.1). The reason for this involves mainly cultural aspects and also the fact that herbal medicines are rarely studied scientifically. Thus, few herbal preparations have been tested for safety and efficacy. The WHO has published guidelines to define basic criteria for evaluating the quality, safety, and efficacy of herbal medicines aimed at assisting national regulatory authorities, scientific organizations, and manufacturers in this particular area. Furthermore, the WHO has prepared Pharmacopeia monographs on herbal medicines and the basis of guidelines for the assessment of herbal drugs.

10.2.1 Characteristics of Phytomedicines

Phytotherapeutic agents or phytomedicines are standardized herbal preparations consisting of complex mixtures of one or more plants, which are used in most countries for the management of various diseases. According to the WHO definition, herbal drugs contain as active ingredients plant parts or plant materials in the crude or processed state plus certain excipients, that is, solvents, diluents, or preservatives.