

REGULATION OF HERBAL MEDICINES IN SEVERAL COUNTRIES

United States

- regulated as "dietary supplements" not drugs
- limitations on health claims (structure/function but not disease or symptoms) and use information

Canada

- regulated mainly (licensed) as OTC drugs
- health claims can be made based upon a "doctrine of reasonable certainty" and documentation of traditional use

Germany

- regulated (licensed) as OTC AND prescription drugs depending upon actions
- health claims can be made supported by: reference in scientific literature or review articles, clinical trials, well-documented "traditional use"
- Commission E oversees regulation of herbal medicines

United Kingdom

- minimal regulation of herbal use and no licensing
- health claims can be made based upon "Traditional Use" but most state that the remedy "has been traditionally used for...."

Ireland

- all herbal medicines are considered as drugs and licensed
- health claims made no different than other drugs

Italy

- herbal medicines classified as either health food products or drugs
- those with any nutritional value not regulated as drugs
- those making therapeutic claims licensed as drugs and sold in pharmacies with prescription

Greece

- All herbal medicines are considered as drugs and licensed
- Proof of efficacy depends upon use (for minor ailments- "history of traditional use"; more severe and/or some toxicity-rigorous clinical and toxicological evaluation)

Switzerland

- herbal medicines have different classifications depending upon indications for use, potential toxicity (several classifications (ex. list C-pharmacy prescription only; list D-pharmacy or drugstore no prescription)
- Extensive information must be provided with all herbal remedies (leaflet)