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ABC Herbal Information Course, Part One: Background on Herbal Medicine

This continuing education (CE) course provides a comprehensive description related to herbs and herbal products to “assist retailers with responses to customer inquiries”. Upon completion of the course, participants are certified for one year by American Botanical Council (ABC) and the National Training Institute (NTI) as herbal information specialists (HIS). The purpose of Part One is to “provide the certification candidate a basic working knowledge about specific use of many popular herbs and herbal products sold in the retail setting, and their relative safety so that he/she will be able to converse with customers on these issues and know the limitations of what can be discussed”. The course includes an introduction, a basic overview on the history of medicinal botanicals; recent market and consumer trends; issues in safety, standardization and regulation; tips for communicating with customers; and interpreting product labels.

Description of the Course:

This course is based on the book “The ABC Clinical Guide to Herbs”. The herbs mentioned in the course were selected because they were some of the top-selling herbal supplements or ingredients in popular herbal teas. Each herb chapter includes a “2-page monograph and a 1-page customer information sheet that is meant to be copied and distributed”. The monograph is a quick-reference and contains an overview, and information on uses, pharmacological actions, dosage and administration, adverse effects, drug interactions, and a clinical review (summary overview of studies).

History/Market and Consumer Trends:

According to the ABC course, “herbs and herbal products have been used widely in the United States up until 1920 when they began to be replaced with pharmaceutical drugs”. The course cites a study from the Journal of the American Medical Association (JAMA) that estimated an increase in herbal usage from the baseline of 2.5% of the adult population (measured in 1990) to 12% of adults using herbs in a one-year period (as measured in 1997), a growth factor of 380%. Also noted is an increase in consumer usage of these products in larger numbers than ever before in the past decade, especially in health and natural food stores, rising 9% from \$123,009,009 in 2000 to \$134,086,587 in 2001.

Safety:

As mentioned in the course, most commercially available herbs are generally gentler and safer than conventional drugs and there are fewer adverse event reports (AERs) in the U.S. for herbs than for conventional pharmaceutical drugs. However, it is noted that the lower AERs may also be due to poor reporting mechanisms or that many herb users may not report adverse events, because they consider these events to be minor. One concern is the potential for interactions with prescription and over-the-counter medications and an

increased risk for adverse herb-drug or drug-supplement interactions. The Slone Survey of 2590 participants concluded that the increased risk for interactions is a concern due to one in seven adults consuming at least one herbal supplement annually and one in six patients taking a prescription drug concurrently with one or more herbal supplements.

Standardization:

The concept standardization can have several meanings: 1) the requirement for Latin binomials and/or standardized common names; 2) guaranteeing specific levels or ranges of certain components to ensure consistency; and 3) “the use of consistent, documented processes and standards throughout every step of production including adherence to Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)”. One misconception is that standardization guarantees potency. However, it is noted that potency is not determined by a single chemical and it is difficult to control all the factors that affect chemical composition.

Regulation:

Dietary supplements are classified as foods but are not intended to replace foods in the diet. They are exempted from the definition of drugs (i.e. intended to diagnose, cure, mitigate, treat, or prevent diseases) and therefore, are not subjected to the same rigorous testing and approval processes for drugs as required by the Food and Drug Administration (FDA). Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, dietary ingredients used in dietary supplements do not require pre-market documentation of safety to the FDA unless they are new dietary ingredients (i.e., ingredients not sold before passage of DSHEA). Once a supplement is on the market, the FDA is required to prove that it is unsafe before imposing restrictions. Supplement labels must carry a “Supplement Facts” panel, with information on ingredients and suggested dosage. One of the primary problems mentioned is the lack of an official system in the US to evaluate and recognize the benefits and risks of herbal preparations. In Germany, The Commission E regulates herbal drugs in much the same way as conventional drugs, including criteria of quality and safety similar to that required for all drugs (although herbal drugs are approved by a standard of “reasonable certainty” as compared to a stricter standard for pharmaceutical drugs). These herbal drugs are also sometimes eligible for reimbursement by the national healthcare system.

Communicating with Consumers:

HIS are encouraged to learn about the potential risks and benefits of herbs, side effects and adverse drug interactions, wide variability among products in chemistry, potency and activity; and reliable references for efficacy, dose, and safety. They should also know what they can legally say to customers about the health benefits of herbs or other dietary supplements based on scientific literature; encourage customers to talk with their healthcare practitioner; and avoid relaying information that might be interpreted as medical advice by providing “printed third party literature (like the Information Sheets

found in Part Two of this course), label and package information, promotional literature, and material from books”.

Interpreting Product Labels

There are 16 areas required on the Supplement Label.

1. Brand name
2. Product/herb name
3. “Statements of nutritional support,” or “structure/function claims,” if they are truthful and not misleading, and documentable by scientific data.
4. If there is a structure/function claim, a FDA disclaimer that the product does not claim to diagnose, cure, treat, or prevent any disease must be included on the product label. The disclaimer must also note that FDA has not evaluated the claim.
5. Number of tablets, capsules, and net weight of each in package.
6. Directions for Use and Cautions
7. “Supplement Facts Panel”
 - a. “Serving Size” is the suggested number of tablets, capsules, softgels, tea bags, liquid extract, or tincture to take at one time.
 - b. “Amount per Serving” indicates the nutrients present in the herb and the quantity.
 - c. “Percent Daily Value” (%DV) indicates the percentage of daily intake provided by the herb.
 - d. “Herbs should be designated by their standardized common names as listed in the book Herbs of Commerce, published in 1992 by the American Herbal Products Association and revised in 2000”. The amount in milligrams of each herb must be listed or the total amount of the blend.
 - e. Standardization. If a product is chemically standardized, the product label may list the component used to measure standardization and the level to which the product is standardized.
 - f. A list of all other ingredients in decreasing order by weight or if multiple herbal ingredients, the herbs must be listed in descending order of predominance.
 - g. Location for storage is typically labeled as a cool, dry place.
 - h. All herbal products and other dietary supplements should be kept out of the reach of children.
 - i. Expiration date.
 - j. Manufacturer or distributor’s name, city, state, and zip code.

Analysis of Course:

The ABC Herbal Course presents a comprehensive view of background issues related to herbs and herbal products. This course is clearly geared toward retailers and HIS. According to the course, it is “accredited” for healthcare professionals including physicians, pharmacists, nurses, dietitians, and others. However, in Part One, information

is not provided as to the process to obtain CE credits, number of credits or the accrediting agencies. The course, especially the extensive description on interpretation of product labels, may be useful as background information for healthcare professionals counseling clients on issues related to herbs and herbal products or for consumers purchasing herbal products in retail stores. However, the cost of \$69.95 for the course (includes Part One and Part Two) may be prohibitive for most consumers. The editors do attempt to provide an unbiased view by acknowledging the benefits and risks, safety issues, poor reporting mechanisms for adverse events, misconception of customers that “just because it is natural does not mean it is safe”; and the growing body of data from controlled clinical trials, although “much of the data on herbs is based on empirical and traditional knowledge”. They also mention the limitation that although a comprehensive literature review was conducted, “the research has not been exhaustive and it is possible that some clinically relevant research information was omitted”.