

WHO Releases New Guidelines on Use and Regulation of Herbal Medicines

By Editorial Staff

The World Health Organization (WHO) has issued a 72-page book titled *Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants*. The guidelines, published this past February, are intended for national regulatory bodies, and include descriptions of the best techniques for growing and harvesting certain types of medicinal plants, along with procedures to provide clear labeling of the contents of any herbal product.

The document "is not a binding guideline for any country, but it is a model, or sort of checklist, which they can use to make their own national regulations," said Dr. Hans Hogerzeil, acting director of the WHO's essential drugs and medicines department.

The objectives of the *Guidelines* are threefold:

1. to ensure the quality of medicinal plant materials used as the source for herbal medicines to improve the quality, safety and efficacy of finished herbal products;
2. to help establish national and/or regional good agricultural and collection practice guidelines and monographs for medicinal plants and related standard operating procedures; and
3. to encourage and support the sustainable cultivation and collection of medicinal plants of good quality, in ways that respect and support the conservation of the environment in general and medicinal plants in particular.

The *Guidelines* were created, Dr. Hogerzeil said, in response to the growing use of medicinal plants worldwide. According to the WHO, the use of herbal medicines accounts for \$60 billion per year in the global market. Up to 50 percent of all herbal preparations are consumed in China, while an estimated 80

percent of the population of Africa relies on traditional medicines, many produced from plants, as a primary form of health care. In the U.S., nearly half of the general population reports using some form of complementary and alternative medicine. Yet only China, Japan and the European Union have established regulations for medicinal plants.

"There is a huge increase in this market," asserted Dr. Hogerzeil. "Many people are paying a lot for traditional medicines, and some insurance systems have started to reimburse (for) traditional remedies. At the same time, this is an area where it is sometimes difficult to regulate properly and get safety assurance for patients."

According to the *Guidelines*, the safety and quality of medicinal plants (and the products they are derived from) depend on a variety of factors. Methods of cultivation, harvesting, processing, transport and storage can all have an impact on the quality of herbal products, as can contamination with chemicals and pesticides, and adulteration from outside sources. All of the above can negatively impact the quality of an herbal remedy, rendering it ineffective or, worse yet, potentially toxic. The *Guidelines* cites several instances in which poor processing procedures or improper identification of plants led to serious side-effects in some patients taking herbal remedies or supplements.

In addition to patient safety issues, there is a growing concern that some medicinal plants are being overharvested. Left uncontrolled, overharvesting or unsustainable harvesting practices could wreak great havoc on the environment, leading to the extinction of entire species of plants, and the destruction of natural habitats and resources. Among the plants the WHO considers at risk of disappearing in the wild are some species of ginseng, goldenseal, echinacea, black cohosh, slippery elm and kava.

To address these concerns, the *Guidelines* provides various practices for agencies interested in harvesting medicinal plants and ensuring their safety and efficacy, many of which are derived from the regulations already in place in Europe and parts of Asia. Among the topics covered in the document are ways to cultivate, collect and classify plants, along with recommendations on quality control, storage, labeling and distribution.

"If we want to preserve the environment and if we want to preserve and sustainably supply these medicines in the future, we have to regulate that, in one way or another," Hogerzeil said.

Bound copies of *Guidelines on Good Agricultural and Collection Practices for Medicinal Plants* can be ordered from the WHO by sending an e-mail to bookorders@who.int. Those with Internet access may also download a copy of the *Guidelines* at www.who.int/medicines/library/trm/medicinalplants/agricultural.shtml.

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