WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants



World Health Organization Geneva 2003

Acknowledgements

The World Health Organization extends its appreciation of the generous support provided by the Government of the Grand Duchy of Luxembourg for the development and publication of these guidelines.

WHO also acknowledges its indebtedness to the more than 240 reviewers, including experts and national authorities, in over 105 countries who provided comments and advice on the draft texts. Preparation of these guidelines benefited, in addition, from technical support received from relevant United Nations agencies, international organizations and nongovernmental organizations.

Special thanks are due to participants of the WHO Consultation on Good Agricultural and Field Collection Practices for Medicinal Plants, held in Geneva, Switzerland in July 2003 to review the draft guidelines (see Annex 6), and to the experts who participated in the WHO Working Group Meeting held in Geneva, Switzerland in October 2003, to review and revise the draft guidelines.

Acknowledgement of their preparation of the original text is also due to: Professor Harry H.S. Fong of the WHO Collaborating Centre for Traditional Medicine, College of Phamacy, University of Illinois at Chicago, Chicago, Illinois, USA; Professor James E. Simon of the New Use Agriculture and Natural Plant Products Program, Cook College, Rutgers University, New Brunswick, New Jersey, USA; and Dr. Jacinto Regalado of the Missouri Botanical Garden, St. Louis, Missouri, USA.

Finally, WHO thanks Health Canada of the Government of Canada, especially the Natural Health Products Directorate, Health Products and Food Branch, which hosted and supported the WHO Informal Meeting on Methodologies for Quality Control of Finished Herbal Products, in Ottawa, Canada in July 2001. It was at this meeting that the idea of developing these guidelines was first discussed and recommended.

The photograph on the front cover was kindly provided by Dr. Setsuko Sekita, Director, Tsukuba Medicinal Plant Research Station, National Institute of Health Sciences, Ministry of Health, Labour and Welfare, Tsukuba, Japan.

Foreword

Traditional medicines, particularly herbal medicines, have been increasingly used worldwide during the last two decades. Unfortunately, the number of reports of patients experiencing negative health consequences caused by the use of herbal medicines has also been increasing. Analysis and studies have revealed a variety of reasons for such problems. One of the major causes of reported adverse events is directly linked to the poor quality of herbal medicines, including raw medicinal plant materials. It has therefore been recognized that insufficient attention has been paid to the quality assurance and control of herbal medicines.

By resolution WHA56.31 on traditional medicine, Member States requested WHO "to provide technical support for development of methodology to monitor or ensure product safety, efficiency and quality, preparation of guidelines, and promotion of exchange of information". WHO has developed a series of technical guidelines relating to the quality control of herbal medicines of which these WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants are the latest. The guidelines provide a detailed description of the techniques and measures required for the appropriate cultivation and collection of medicinal plants and for the recording and documentation of necessary data and information during their processing.

Despite such guidelines, there is still considerable disparity between knowledge and implementation. For example, it is a difficult task to train farmers and other relevant persons as producers, handlers and processors of medicinal plant materials. While pharmaceutical and other companies are striving to meet the requirements for the quality control of herbal medicines, they cannot force farmers, producers, handlers and processors to follow good agricultural and collection practices for medicinal plants. The training of farmers and other relevant persons is therefore one of many important measures to be taken to ensure that good agricultural and collection practices are adopted in order that medicinal plant materials of high quality are obtained.

Quality control directly impacts the safety and efficacy of herbal medicinal products. Good agricultural and collection practices for medicinal plants is only the first step in quality assurance, on which the safety and efficacy of herbal medicinal products directly depend upon, and will also play an important role in the protection of natural resources of medicinal plants for sustainable use. Until now, only the European Union and a few countries, such as China and Japan have developed regional and national guidelines for good agricultural and collection practices for medicinal plants.

We believe that more countries will develop their own guidelines for the quality control of medicinal plants based on the guidelines developed by WHO. However, there is still a long way to go before such guidelines are implemented worldwide, and cooperative efforts on the part of national authorities, including health, agricultural, trade and research institutes, and nongovernmental organizations will be needed to enable us to reach our goal.

Dr Xiaorui Zhang

Coordinator Traditional Medicine (TRM) Department of Essential Drugs and Medicines Policy (EDM) World Health Organization

Contents

Ack	cnowled	dgements	i
For	eword .		ii
Cor	ntents		v
1.	Gener	al introduction	1
1.1		sground	
1.2	Obje	ectives	2
1.3	Stru	cture	3
1.4	Glos	ssary	4
	1.4.1.	Terms relating to herbal medicines:	4
	1.4.2. 7	Terms relating to medicinal plant cultivation and collection act	tivities:.5
2.	Good	agricultural practices for medicinal plants	7
2.1		ntification/authentication of cultivated medicinal plants	
	2.1.1	Selection of medicinal plants	
	2.1.2	Botanical identity	
	2.1.3	Specimens	
2.2		ds and other propagation materials	
2.3		tivation	
	2.3.1	Site selection	
	2.3.2	Ecological environment and social impact	
	2.3.3	Climate	
	2.3.4	Soil	
	2.3.5	Irrigation and drainage	
	2.3.6	Plant maintenance and protection	
2.4		vest	
2.5	Pers	sonnel	12
3.		collection practices for medicinal plants	
3.1		mission to collect	
3.2		nnical planning	
3.3		ction of medicinal plants for collection	
3.4		ection	
3.5	Pers	sonnel	16
4.		non technical aspects of good agricultural practices for me	
_		good collection practices for medicinal plants	
4.1		t-harvest processing	
	4.1.1	Inspection and sorting	17

	4.1.2	Primary processing.	
	4.1.3	Drying	18
	4.1.4	Specific processing	19
	4.1.5	Processing facilities	19
4.2	Bulk p	packaging and labelling	23
4.3	Storag	ge and transportation	24
4.4	Equip	ment	24
	4.4.1	Materials	
	4.4.2	Design, construction and installation	24
	4.4.3	Identification	25
4.5	Qualit	ty assurance	25
4.6		nentation	
4.7	Person	nnel (growers, collectors, producers, handlers, processors).	26
	4.7.1	General	
	4.7.2	Health, hygiene and sanitation	26
5.	Other re	elevant issues	29
5.1		l and legal considerations	
0.1	5.1.1	Intellectual property rights and benefits-sharing	
	5.1.2	Threatened and endangered species	
5.2	Resea	rch needs	
D'L	1 1.		21
BID	liograph	y	31
		Good Agricultural Practice for Traditional Chinese Meople's Republic of China	
		ints to Consider on Good Agricultural and Collection Praterials of Herbal Origin	
		ood Agricultural and Collection Practices for Medicina	
		nodel structure for monographs on good agricultural practicinal plants	ctices for 61
Δnı	10v 5 S21	nnla record for cultivated medicinal plants	65

预览已结束, 完整报告链接和二维码如下:

https://www.yunbaogao.cn/report/index/report?reportId=5_30151

